

# RYONCIL- remestemcel-L-rknd Mesoblast

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use RYONCIL® safely and effectively. See full prescribing information for RYONCIL®.

**RYONCIL® (remestemcel-L-rknd) suspension for intravenous infusion**

**Initial U.S. Approval: December 2024**

## RECENT MAJOR CHANGES

How Supplied/Storage and Handling (16)

09/2025

## INDICATIONS AND USAGE

RYONCIL is an allogeneic bone marrow-derived mesenchymal stromal cell (MSC) therapy indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older. (1)

## DOSAGE AND ADMINISTRATION

**For intravenous use only. (2)**

- The recommended dosage of RYONCIL is  $2 \times 10^6$  MSC/kg body weight per intravenous infusion given twice per week for 4 consecutive weeks. Infusions should be administered at least 3 days apart.
- Assess response  $28 \pm 2$  days after the first dose and administer further treatment as appropriate as described in the table below.

Recommended Treatment Based on Day 28 Response	
Response	Recommendation
Complete Response (CR)	No further treatment with RYONCIL
Partial or Mixed Response	Repeat administration of RYONCIL once a week for additional 4 weeks (4 infusions total)
No Response	Consider alternative treatments
Recurrence of GvHD after CR	Repeat administration of RYONCIL twice a week for an additional 4 consecutive weeks (8 infusions total)

## DOSAGE FORMS AND STRENGTHS

RYONCIL is available as a cell suspension for intravenous infusion in a target concentration of  $6.68 \times 10^6$  MSCs per mL in 3.8 mL contained in a 6 mL cryovial. (3)

## CONTRAINDICATIONS

Known hypersensitivity to dimethyl sulfoxide (DMSO) or Porcine and Bovine proteins. (4)

## WARNINGS AND PRECAUTIONS

Hypersensitivity/Acute Infusion reactions: Monitor for hypersensitivity reactions during infusion and premedicate with corticosteroids and antihistamines. (5.1)

Transmission of Infectious Agents: RYONCIL may transmit infectious agents. (5.2)

Ectopic Tissue Formation: Ectopic tissue formation may occur following treatment with RYONCIL. (5.3)

## ADVERSE REACTIONS

The most common non-laboratory adverse reactions (incidence  $\geq 20\%$ ) are: viral infectious disorders, bacterial infectious disorders, infection – pathogen unspecified, pyrexia, hemorrhage, edema, abdominal pain and hypertension (6.1).

**To report SUSPECTED ADVERSE REACTIONS, contact Mesoblast at toll-free phone #1-844-889-MESO (6376) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**See 17 for PATIENT COUNSELING INFORMATION.**

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\* Sections or subsections omitted from the full prescribing information are not listed.

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## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

RYONCIL is indicated for the treatment of steroid refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

### **2 DOSAGE AND ADMINISTRATION**

**For intravenous use only.**

## 2.1 Recommended Dosage

- The recommended dosage of RYONCIL is  $2 \times 10^6$  mesenchymal stromal cells (MSC)/kg body weight per intravenous infusion given twice a week for 4 consecutive weeks for a total of 8 infusions. Administer infusions at least 3 days apart.
- Assess response  $28 \pm 2$  days after the first dose and administer further treatment as appropriate as described in Table 1 based on Day 28 response.

**Table 1: Recommended Treatment based on Day 28 Response**

Response	Recommendation
Complete Response	No further treatment with RYONCIL
Partial or Mixed Response*	Repeat administration of RYONCIL once a week for additional 4 weeks (4 infusions total)
No Response	Consider alternative treatments
Recurrence of GvHD after complete response	Repeat administration of RYONCIL twice a week for an additional 4 consecutive weeks (8 infusions total)

\* Partial response defined as organ improvement of at least one stage without worsening in any other organ, whereas mixed response was defined as improvement of at least one evaluable organ with worsening in another organ as per International Blood and Marrow Transplantation Registry Severity Index Criteria grading system.

## 2.2 Preparation and Administration Instructions

### Receipt and Storage of RYONCIL

RYONCIL is shipped directly to the clinical facility in a liquid nitrogen dry shipper maintained at a temperature of  $\leq -135^\circ\text{C}$ .

RYONCIL must remain frozen at  $\leq -135^\circ\text{C}$  in liquid nitrogen vapor phase until thawed immediately prior to administration [see *How Supplied/Storage and Handling (16)*].

### Preparation

RYONCIL and Plasma-Lyte® A should be prepared following aseptic technique in a Biological Safety Cabinet (BSC). Spray and wipe down the following materials with 70% alcohol prior to transferring them into the BSC preparation area. All materials should remain in the BSC preparation area unless discarded.

Prepare a sterile water bath to a minimum depth of 4 inches and warm to  $37^\circ\text{C}$  ( $\pm 2^\circ\text{C}$ ) at least 30 minutes prior for thawing.

Supplies needed for preparation of RYONCIL and Plasma-Lyte® A

- RYONCIL vials
- Plasma-Lyte® A
- Infusion bag
- Interlink blood bag spikes (2)
- Interlink threaded lock cannula (1 per syringe)
- 60 mL luer-lock syringe (1)
- 5 mL luer-lock syringe (1 per each thawed vial)

- 18-gauge needle (1 per each thawed vial)  
*Note: Use a 1mL syringe if volume to be removed from vial is less than 1mL*
- Airtight zip seal plastic bag(s) (1 per each vial for thaw)
- Water bath
- Alcohol wipes

*Note: Plasma-Lyte® A may be substituted by Plasma-Lyte® 148 (pH 7.4 with no glucose).*

#### *Preparation of Plasma-Lyte® A*

- 1- Insert the Interlink blood bag spike into the Plasma-Lyte® A bag.
- 2- Aseptically attach the threaded lock cannula to a 60 mL syringe.
- 3- Use an alcohol wipe to scrub the membrane of the Plasma-Lyte® A bag interlink spike injection site.
- 4- Attach the threaded lock cannula/syringe assembly to the Plasma-Lyte® A bag to the injection site.
- 5- Measure and withdraw 40 mL of Plasma-Lyte® A from the bag

*Note: DO NOT remove the syringe containing Plasma-Lyte® A from the Plasma-Lyte® A bag. Set aside for later use.*

#### *Preparation of RYONCIL*

1. Prior to RYONCIL thaw, verify that the pre-arranged time for the RYONCIL administration is still feasible. Patient infusion must occur within 5 hours from the start time of first vials of RYONCIL thaw.
2. Remove RYONCIL vial(s) from cryo-storage.
3. Place vial(s) into an airtight zip seal plastic bag(s) and immerse closed bag(s) into the water bath (37°C), maintaining the top closure above the water line. Use a separate zip seal plastic bag for each vial of RYONCIL.  
*Note: A maximum of 4 vials can be thawed in the water bath at the same time.*
4. To thaw, gently agitate the sealed zip seal bag(s) with the vial(s) for approximately 5 to 8 minutes to thaw.
5. Remove vials from the water bath prior to the last visible crystal of ice melting.  
*Note: Do not exceed 15 minutes for each set of four vials.*
6. Inspect vial(s) while still in the bag(s) to identify there is no leakage of vial contents.
7. Remove the RYONCIL vial(s) from the sealed plastic bag(s).
8. Inspect for foreign particulate matter (FPM). If FPM is found via visual inspection – DO NOT USE! Retain the offending vial(s). Call the Mesoblast contact number 844-889-MESO (6376).
9. Remove the tab from the RYONCIL vial cap to expose the vial stopper and wipe the exposed surface of the stopper with one provided sterile alcohol wipe.
10. Promptly withdraw the required amount of RYONCIL (based on actual patient body weight) from the vial(s). One syringe and an 18-gauge needle per thawed vial is required.
11. Carefully remove the needle from the syringe containing RYONCIL.
12. Attach the threaded lock cannula to the syringe.
13. Retrieve the infusion bag.
14. Wipe the membrane of the infusion bag interlink spike injection site with sterile alcohol wipe.

15. Insert 1 interlink blood bag spike into the outermost port on the infusion bag (leave the middle port for the infusion line.)
16. Attach the syringe to the spike and transfer the RYONCIL into the infusion bag.
17. Remove the syringe with the threaded lock cannula and discard the syringe and the threaded lock cannula.
18. Repeat for each syringe until the required volume of RYONCIL is added to the infusion bag.

#### *Transfer of Plasma-Lyte® A into Infusion Bag*

1. Retrieve the bag and 60 mL syringe containing Plasma-Lyte® A.
2. Verify the syringe contains 40mL of Plasma-Lyte® A.
3. Aseptically remove the 60 mL syringe with the threaded lock cannula containing the 40mL Plasma-Lyte® from the bag of Plasma-Lyte® A.
4. Use alcohol wipes to clean the membrane of the infusion bag interlink spike injection site.
5. Aseptically attach the 60mL syringe containing the Plasma-Lyte® A to the spike.
6. Slowly transfer the 40mL Plasma-Lyte® A into the infusion bag.
7. Gently mix cells with the Plasma-Lyte® A.
8. Remove the syringe with the threaded lock cannula and discard the syringe and threaded lock cannula.
9. Label the bag according to Institutional Policy.
10. Transport infusion bag to patient infusion area.

### **Administration**

*Note: Patient infusion must occur within 5 hours from the start time of first vial(s) of RYONCIL thaw.*

- Administer RYONCIL under the supervision of a qualified health professional experienced in the management of SR-aGvHD.
- Administer RYONCIL using an infusion pump.
- Use blood filter with a pore size of 40-260 microns for infusion of RYONCIL.
- Flush lines per institutional practice and/or policy for cellular infusions.
- Pretreatment  
Premedicate patients with corticosteroids and antihistamines 30-60 minutes prior to administration of RYONCIL to reduce the potential for infusion reactions.
- Infusion Rates
  - For patients weighing 35 kg or more, infuse RYONCIL at a rate of no more than 6mL/ minute.
  - For patients weighing less than 35 kg, infuse RYONCIL over the course of 60 minutes.
- Discard unused, thawed RYONCIL vials per institutional policy.

### **3 DOSAGE FORMS AND STRENGTHS**

RYONCIL is available as a cell suspension for intravenous infusion in a target concentration of  $6.68 \times 10^6$  MSCs per mL in 3.8 mL at cryopreservation contained in a 6 mL cryovial.

Each 6 mL cryovial contains approximately  $25 \times 10^6$  MSCs.

Cryopreserved MSCs are combined with Plasma-Lyte® A for administration.

## **4 CONTRAINDICATIONS**

Do not use RYONCIL in patients with known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins.

## **5 WARNINGS AND PRECAUTIONS**

### **5.1 Hypersensitivity and Acute Infusion Reactions**

Hypersensitivity reactions including acute infusion reactions have occurred with RYONCIL administration [see *Adverse Reactions (6.1)*]. Serious hypersensitivity reactions, including anaphylaxis, may occur due to DMSO and trace amounts of porcine or bovine proteins. Signs and symptoms may include fever, dyspnea, and hypotension during or after RYONCIL infusion.

Premedicate patients with antihistamine and corticosteroids and monitor closely for signs and symptoms of hypersensitivity or acute infusion reactions.

If a hypersensitivity or infusion reaction occurs, interrupt RYONCIL infusion. Do not administer RYONCIL in patients who experience serious or life-threatening reactions.

### **5.2 Transmission of Infectious Agents**

Transmission of infectious disease or agents may occur with RYONCIL administration because it contains cells from human donors and is manufactured using human, porcine and bovine-derived reagents. Donors are screened and tested for Human Immune-deficiency Virus 1 (HIV-1); Human Immune-deficiency Virus 2 (HIV-2); Hepatitis B Virus (HBV); Hepatitis C Virus (HCV); Human T-cell Leukemia-lymphoma Virus 1 (HTLV-1); Human T-cell Leukemia-lymphoma Virus 2 (HTLV-2); West Nile Virus (WNV); Cytomegalovirus (CMV); Epstein-Barr Virus (EBV); and Syphilis (*Treponema pallidum*). Only screening was performed for Creutzfeldt-Jakob disease (CJD) and communicable disease risks associated with xenotransplantation. RYONCIL cell banks are tested for human and animal viruses, retroviruses, bacteria, fungi, yeast, and mycoplasma. Human and animal-derived reagents are tested for human and animal viruses, bacteria, fungi, and mycoplasma before use. These measures do not eliminate the risk of transmitting these or other infectious diseases or agents.

### **5.3 Ectopic Tissue Formation**

Ectopic tissue formation may occur following treatment with RYONCIL due to the ability of human mesenchymal stromal cells to differentiate into mesenchymal lineage cells such as bone, cartilage and fat cells.

## **6 ADVERSE REACTIONS**

### **6.1 Clinical Trials Experience**

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in

the clinical studies of another drug and may not reflect the rates observed in practice.

The safety data described in this section reflect exposure to RYONCIL in 54 patients in Study MSB-GVHD001 for the treatment of SR-aGvHD. Patients received intravenous infusion of RYONCIL at a dosage of  $2 \times 10^6$  MSCs/kg twice a week for four consecutive weeks, for a total of eight infusions. Patients with partial or mixed response at Day 28 received additional infusions of RYONCIL  $2 \times 10^6$  MSCs/kg once a week for an additional four weeks [see *Clinical Studies (14)*]. The median number of doses administered were 10 (range 1 to 16), and the treatment was administered over a median of 43 days (range 1 to 104 days).

Serious adverse reactions occurred in 35 patients (65%) including pyrexia (n=5;9%), respiratory failure (n=5;9%), pneumatosis intestinalis (n=4;7%) and staphylococcal bacteremia (n=2;<5%). Eight patients had discontinuation of RYONCIL treatment due to the following: acute infusion reactions (n=3), hypotension (n=1), gastroenteritis (n=1), and death (n=3).

Table 2 summarizes most common adverse reactions that occurred in  $\geq 10\%$  patients in Study MSB-GVHD001.

**Table 2: Adverse Reactions\*\* Occurring in  $\geq 10\%$  of Patients in Study MSB-GVHD001 (N=54)**

Adverse Reactions	All Grades <sup>a</sup> n (%)	Grade 3 <sup>b</sup> n (%)
Viral infectious disorders*	30 (56)	8 (15)
Bacterial infectious disorders*	24 (44)	10 (19)
Infections - pathogen unspecified*	22 (41)	8 (15)
Pyrexia	19 (35)	2 (4)
Hemorrhage*	15 (28)	4 (7)
Edema*	12 (22)	1 (2)
Abdominal pain	11 (20)	4 (7)
Hypertension	11 (20)	3 (6)
Vomiting	10 (19)	3 (6)
Arrhythmia*	9 (17)	2 (4)
Diarrhea	9 (17)	1 (2)
Rash*	9 (17)	0 (0)
Arthralgia	8 (15)	0 (0)
Fungal infectious disorders*	8 (15)	2 (4)
Hypotension	8 (15)	2 (4)
Cough	7 (13)	0 (0)
Respiratory Failure	6 (11)	6 (11)

<sup>a</sup> Based on National Cancer Institute Adverse Event Common Toxicity Criteria version 4.03

<sup>b</sup> No grade 4 or 5 adverse reactions occurred in the study  
\*Is a composite that includes multiple related terms  
\*\*Includes adverse reactions up to 100 days following RYONCIL treatment

Table 3 presents the most common grade 3 or 4 laboratory abnormalities that worsened from baseline in  $\geq 10\%$  of patients

**Table 3: Grade 3 or 4 Laboratory Abnormalities that Worsened from Baseline in  $\geq 10\%$  of Patients in Study MSB-GVHD001 (N=54)**

<b>Laboratory Parameter</b>	<b>Grade 3 or higher<sup>a</sup> %</b>
Gamma-glutamyl transferase increased	32
Thrombocytopenia	28
Blood bilirubin increased	11

<sup>a</sup> Based on National Cancer Institute Adverse Event Common Toxicity Criteria version 4.03

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

#### Risk Summary

There are no available data for RYONCIL use in pregnant women. No animal reproductive and developmental toxicity studies have been conducted with RYONCIL to assess whether it can cause fetal harm when administered to a pregnant woman. It is not known if RYONCIL has the potential to be transferred to the fetus. Therefore, RYONCIL is not recommended for women who are pregnant. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 10-20%, respectively.

### **8.2 Lactation**

#### Risk Summary

There is no information regarding the presence of RYONCIL in human milk, the effect on the breastfed infant, and the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RYONCIL and any potential adverse effects on the breastfed infant from RYONCIL or from the underlying maternal condition.

### **8.4 Pediatric Use**

The safety and effectiveness of RYONCIL for treatment of SR-GvHD have been established in pediatric patients 2 months of age and older. The use of RYONCIL in these age groups is supported by evidence from an adequate and well-controlled trial [see



## **11 DESCRIPTION**

RYONCIL is provided as a frozen cell suspension in a cryogenic vial. The active ingredient in RYONCIL is comprised of culture-expanded mesenchymal stromal cells (MSCs) isolated from the bone marrow of healthy human adult donors. Each cryovial contains nominally  $25 \times 10^6$  MSCs in 3.8 mL (a target concentration  $6.68 \times 10^6$  cells/mL) formulated in Plasma Lyte<sup>®</sup>-A (70% v/v), Human Serum Albumin (HSA) Solution (25%) (20% v/v) and Dimethyl sulfoxide (DMSO) (10% v/v). The product is thawed and combined with Plasma-Lyte<sup>®</sup> A prior to intravenous administration.

## **12 CLINICAL PHARMACOLOGY**

### **12.1 Mechanism of Action**

The mechanism of action for RYONCIL is not clear but may be related to immunomodulatory effects. Data from in vitro studies demonstrate that MSCs inhibit T cell activation as measured by proliferation and secretion of pro-inflammatory cytokines. Acute GvHD occurs when alloreactive donor-derived T cells within the donated tissue (graft) trigger an immunological response, and alloreactive donor-derived T cells play a role in mediating the systemic inflammation, cytotoxicity and potential end organ damage associated with aGvHD.

### **12.2 Pharmacodynamics**

Human pharmacodynamic data were obtained from analysis of blood samples in pediatric subjects with SR-aGvHD (n=40; age range 0.6-17 years) following treatment with RYONCIL at a dose of  $2 \times 10^6$  cells/kg. At Baseline, elevated levels of tumor necrosis factor receptor type I (TNFR1) and suppressor of tumorigenicity 2 (ST2) were observed consistent with the inflammatory state of aGvHD. Treatment with RYONCIL reduced the levels of TNFR1 and ST2 by 79% and 75%, respectively, at Day 180 as compared to baseline values. Further, the circulating levels of CD3+CD4+CD25+HLA-DR+ T cells, which represent activated T cells, were reduced by 64% at Day 180 following treatment with RYONCIL as compared to the baseline values.

### **12.3 Pharmacokinetics**

No studies have been performed to evaluate the pharmacokinetics of RYONCIL.

## **13 NONCLINICAL TOXICOLOGY**

### **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

No animal studies have been performed to evaluate the effects of RYONCIL on carcinogenesis, mutagenesis or impairment of fertility.

## **14 CLINICAL STUDIES**

The efficacy of RYONCIL was evaluated in a multicenter, prospective, single-arm study (MSB-GVHD 001; NCT02336230). The study enrolled pediatric patients with SR-GvHD Grade B to D (excluding Grade B skin alone) as per International Blood and Marrow Transplantation Registry Severity Index Criteria (IBMTR) after receiving allogeneic hematopoietic stem cell transplantation (HSCT). SR-aGvHD was defined as aGvHD that progressed within 3 days or did not improve within 7 consecutive days of treatment with methylprednisolone 2 mg/kg/day or equivalent. Patients who received a second line therapy for aGvHD prior to screening were excluded.

RYONCIL was administered by intravenous infusion at a dosage of  $2 \times 10^6$  MSCs/kg twice a week for four consecutive weeks, for a total of eight infusions. Patients with partial or mixed response at Day 28 received additional infusions of RYONCIL  $2 \times 10^6$  MSCs/kg once a week for an additional four consecutive weeks. Patients with complete response at Day 28 who experienced recurrence of aGvHD received infusions of RYONCIL  $2 \times 10^6$  MSCs/kg twice a week for an additional four consecutive weeks.

A total of 55 patients were enrolled, and 54 were treated with RYONCIL. Among the treated patients (n=54), the demographic characteristics were as follows: median age was 7 years (range: 7 months to 17 years); 36% were females; 56% were White, 19% reported “other” race, 15% were Black, 6% were Asian, 6% American Indian or Alaska Native, 33% were Hispanic and 65% were non-Hispanic. Among enrolled patients, hematologic malignancies (67%) and non-malignant diseases (33%) were the underlying reasons for allogeneic HSCT. SR-GvHD severity was as follows at baseline: Grade B (11%), Grade C (43%), Grade D (46%). Organ involvement at baseline were as follows: skin alone (26%), lower gastrointestinal tract only (39%), multi-organ involvement (35%). The median duration of prior corticosteroid treatment at baseline was 8 days (range: 2 to 46 days).

The main efficacy outcome measures were Day-28 overall response rate (complete response rate and partial response rate) and the duration of response.

The efficacy results are summarized in Table 4.

**Table 4: Efficacy Results for Study MSB-GVHD001**

<b>Response at Day 28</b>	<b>N=54</b>
Overall Response Rate n (%) 95% CI <sup>a</sup>	38 (70%) 56.4, 82.0
Duration <sup>b</sup> (days) Median (range)	54 (7, 159+)
Complete Response Rate <sup>c</sup> n (%) 95% CI <sup>a</sup>	16 (30%) 18.0, 43.6
Partial Response Rate <sup>d</sup> n (%) 95% CI <sup>a</sup>	22 (41%) 27.6, 55.0

CI=confidence interval

<sup>a</sup> Two-sided exact binomial confidence interval at the 95% level

<sup>b</sup> Duration of response was calculated from Day-28 response to either progression (worsening by one stage in any organ without improvement in other organs in comparison to prior response assessment), new systemic therapy for aGvHD or death from any cause.

<sup>c</sup> Complete response was defined as resolution of aGvHD in all involved organs as per IBMTR grading system.

<sup>d</sup> Partial response was defined as organ improvement of at least one stage without worsening of any other organ as per IBMTR grading system.

Overall response rate at Day 28 by baseline disease severity is as follows: Grade B (3/6; 50%), Grade C (16/23; 70%), and Grade D (19/25; 76%).

Among the 38 responders, the median time from Day-28 response to either death or need for systemic therapy for aGvHD (non-RYONCIL systemic therapy for aGvHD or increase in the dose of corticosteroids to methylprednisolone 2 mg/kg or equivalent) was 111.5 days (range 9, 182+).

## 16 HOW SUPPLIED/STORAGE AND HANDLING

RYONCIL is supplied as a sterile, cryopreserved cell suspension of *ex-vivo* culture-expanded allogeneic bone marrow-derived mesenchymal stromal cells (MSC) in vials.

RYONCIL is provided as a customized kit to meet dosing requirements for a single dose for each patient [see *Dosage and Administration (2.1)*], with each kit containing:

- Cartons containing sufficient RYONCIL for one infusion based on the patient weight (see Table 5)
- Sufficient alcohol wipes for preparation of the RYONCIL infusions.

Kit sizes and National Drug Codes (NDC) are provided in Table 5.

**Table 5: RYONCIL Kit Sizes**

Patient weight (kg)	Kit contents (single infusion)					Number of kits needed for:		
	4-vial cartons	1-vial cartons	Total cartons	Number of alcohol wipes	NDC Number	Initial course	2 <sup>nd</sup> course	Relapse after CR
<12.5	0	1	1	1	73648-111-01			
12.5- <25	0	2	2	2	73648-112-02			
25- <37.5	0	3	3	3	73648-113-03			
37.5- <50	1	0	1	4	73648-114-01			
50					73648-115-01			

50- <62.5	1	1	2	5	73648- 115-02	8	4	8
62.5- <75	1	2	3	6	73648- 116-03			
75- <87.5	1	3	4	7	73648- 117-04			
87.5- <100	2	0	2	8	73648- 118-02			
100- <112.5	2	1	3	9	73648- 119-03			
112.5- <125	2	2	4	10	73648- 120-04			
125- <137.5	2	3	5	11	73648- 121-05			
137.5- <150	3	0	3	12	73648- 122-03			

RYONCIL is shipped to the clinical facility in a liquid nitrogen dry shipper maintained at a temperature of  $\leq -135^{\circ}\text{C}$ .

Storage conditions: RYONCIL must remain frozen at  $\leq -135^{\circ}\text{C}$  in liquid nitrogen vapor phase until thawed immediately prior to administration.

Handling: Restrict preparation and administration of RYONCIL to a medical facility in which the medical personnel are trained in aseptic technique.

Disposal: Dispose empty or partially used RYONCIL vials according to the institutional guidelines for disposal of biohazard materials.

*Do not save thawed RYONCIL vials for future use.*

## 17 PATIENT COUNSELING INFORMATION

Discuss the following with patients and/or caregivers.

- Hypersensitivity and Acute infusion reactions: Inform patients and/or caregivers that hypersensitivity and acute infusion reactions due to the presence of porcine and bovine protein, and DMSO may occur with RYONCIL infusion. Advise patients and/or caregivers to seek immediate medical evaluation if any signs and symptoms of hypersensitivity or acute infusion reactions occur, such as fever, rash or hives, low blood pressure, breathing problems [see *Warnings and Precautions (5.1)*].
- Transmission of Infectious Agents: Inform patients and/or caregivers about the possible risk of transmission of infectious agents with RYONCIL administration [see *Warnings and Precautions (5.2)*].
- Ectopic Tissue Formation: Inform patients and/or caregivers about the possible risk of ectopic tissue formation with RYONCIL administration [see *Warnings and Precautions (5.3)*].

Manufactured for:  
Mesoblast, Inc.  
1114 Sixth Avenue, Fourth Floor  
New York, NY 10036

US License number: 2140

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V 3

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

**remestemcel-L-rknd**

**Ryoncil®**

Target  $25 \times 10^6$ / 3.8mL  
( $6.68 \times 10^6$ /mL)

### **For intravenous administration after thaw and resuspension**

See Prescribing Information for directions for use.

Store at  $\leq -135^\circ\text{C}$

Single-use vial

Discard unused portion

Manufactured for Mesoblast Inc.

Rx only

<b>remestemcel-L-rknd</b> <b>Ryoncil®</b>  Target $25 \times 10^6$ / 3.8mL ( $6.68 \times 10^6$ /mL)	<b>For intravenous administration after thaw and resuspension</b> See Prescribing Information for directions for use. Store at $\leq -135^\circ\text{C}$ Single-use vial Discard unused portion  Manufactured for Mesoblast Inc.	<b>Rx only</b>	<b>2D CODE</b>	<b>Lot: XXXXXX</b> <b>Exp: MMMYYY</b>	<b>PNTC-1154.010</b>
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## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 73648-**154**-01

**remestemcel-L-rknd**

**Ryoncil®**

### **Suspension for IV Infusion**

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6$ / 3.8mL ( $6.68 \times 10^6$ /mL)

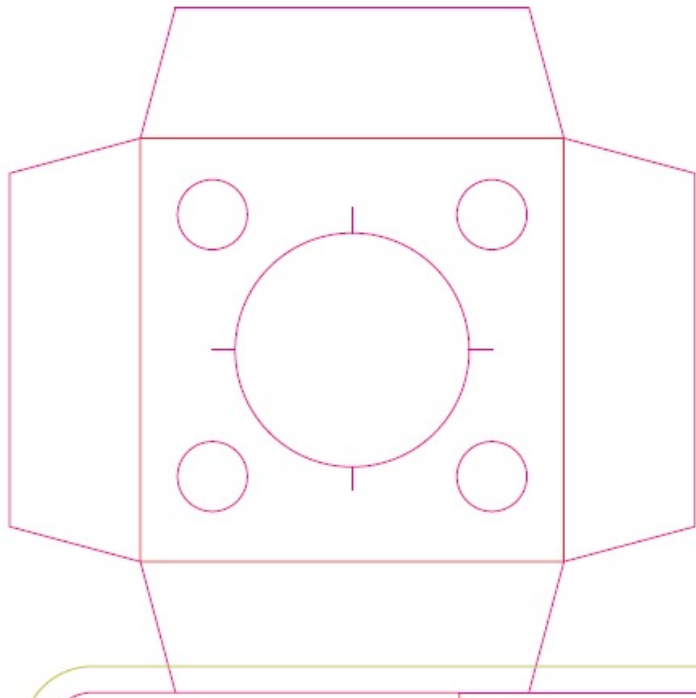
Single-use vial. Discard unused portion.

### **For intravenous administration after thaw and resuspension**

Rx only

Sterile. No preservative.





NDC 73648-154-01

# remestemcel-L-rknd Ryoncil<sup>®</sup>

## Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6 / 3.8 \text{ mL}$  ( $6.68 \times 10^6 / \text{mL}$ )

Single-use vial. Discard unused portion.

For intravenous administration after  
thaw and resuspension

Rx only

Sterile. No preservative.

PNTC-1154011

mesoblast

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1114 Sixth Avenue, Fourth Floor  
New York, NY 10036  
US License number: 2140



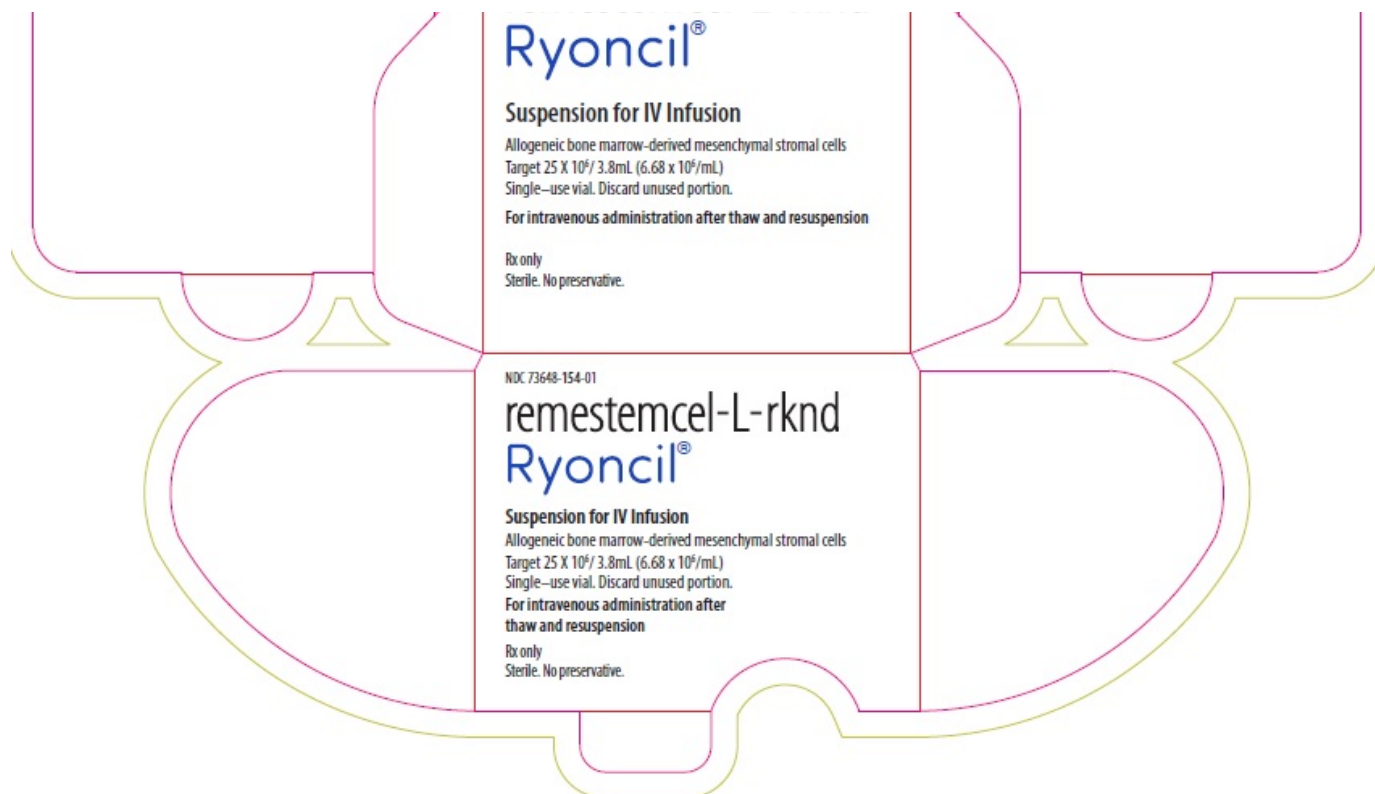
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NDC 73648-154-01

# remestemcel-L-rknd

See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and  
resuspension of RYONCIL<sup>®</sup>.  
Contains 1 vial.  
Each vial contains at least  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution  
20% v/v (containing 5% w/v Human Serum  
Albumin), Plasma-Lyte-A/70% w/v, dimethyl sulfoxide  
(DMSO) 10% w/v.  
Contains known sensitizing substances (MISO or Potent and  
ANDP RECAUTIONS).  
Bovine protein (see Prescribing Information, WARNINGS  
AND PRECAUTIONS).  
Store at  $-135^{\circ}\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.



## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 73648-**154**-04

**remestemcel-L-rknd**

**Ryoncil®**

### **Suspension for IV Infusion**

Allogeneic bone marrow-derived mesenchymal stromal cells

Target 25 X 10<sup>6</sup>/ 3.8mL (6.68 x 10<sup>6</sup>/mL)

Single-use vial. Discard unused portion.

### **For intravenous administration after thaw and resuspension**

Rx only

Sterile. No preservative.



NDC 73648-154-04

## remestemcel-L-rknd Ryoncil®

### Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target 25 X 10<sup>6</sup> / 3.8mL (6.68 x 10<sup>6</sup>/mL)

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

PNTC-1154.012

See Prescribing Information for directions for use.  
Complete infusion within **5 HOURS** of thawing and  
resuspension of RYONCIL®.  
Contains 4 vials.  
Each vial contains at least 25 x 10<sup>6</sup> cells / 3.8 mL  
Cryopreserved in: Human Serum Albumin Solution  
20% v/v (containing 5% w/v Human Serum  
Albumin), Phosphate-buffered saline (pH 7.0) with 0.1%  
(DMSO) 10% w/v.  
Contains known sensitizing substances (DMSO or Polysorbate  
and Bovine proteins) (see Prescribing Information for  
WARNINGS AND PRECAUTIONS).  
Store at ≤ -135°C; vapor phase of liquid nitrogen  
No U.S. standard of potency.

LOT: XXXXXX  
EXP: MMYYYY



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U.S. License number: 2140

NDC 73648-154-04

## remestemcel-L-rknd Ryoncil®

### Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target 25 X 10<sup>6</sup> / 3.8mL (6.68 x 10<sup>6</sup>/mL)

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

NDC 73648-154-04

## remestemcel-L-rknd Ryoncil®

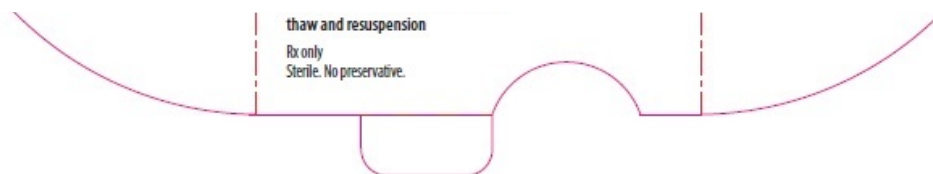
### Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target 25 X 10<sup>6</sup> / 3.8mL (6.68 x 10<sup>6</sup>/mL)

Single-use vial. Discard unused portion.

For intravenous administration after



## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 73648-111-01  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
<12.5 kg

Kit Contents:  
1 X single vial carton  
1 Alcohol Wipe

Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

Manufactured for Mesoblast Inc.  
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GTIN: XXXXXXXXXXXXXXXX  
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PNTC-1154.024

NDC 73648-111-01  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
<12.5 kg

Kit Contents:  
1 X single vial carton  
1 Alcohol Wipe



Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

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New York, NY 10036  
U.S. License number: 2140



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PNTC-1154.024

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 73648-112-02  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:

12.5 kg – <25 kg

Kit Contents:

2 X single vial cartons

2 Alcohol Wipes

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v

(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

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U.S. License number: 2140

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PNTC-1154.025

NDC 73648-112-02  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$ / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
12.5 kg – <25 kg

Kit Contents:  
2 X single vial cartons  
2 Alcohol Wipes



Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

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New York, NY 10036  
U.S. License number: 2140



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PNTC-1154.025

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 73648-113-03  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$ / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:

25 kg - <37.5 kg

Kit Contents:

3 X single vial cartons

3 Alcohol Wipes

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v

(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^{\circ}\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

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U.S. License number: 2140

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PNTC-1154.026

NDC 73648-113-03  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$ / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
25 kg – <37.5 kg

Kit Contents:  
3 X single vial cartons  
3 Alcohol Wipes



Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

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New York, NY 10036  
U.S. License number: 2140



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PNTC-1154.026

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 73648-114-01  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$ / 3.8mL ( $6.68 \times 10^6$ /mL)



Kit for Patient Weight:

37.5 kg – <50 kg

Kit Contents:

1 X 4-vial carton

4 Alcohol Wipes

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v

(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

1114 Sixth Avenue, Fourth Floor

New York, NY 10036

U.S. License number: 2140

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LOT: XXXXXXXX

EXP: MMMYYYY

PNTC-1154.027



NDC 73648-114-01

remestemcel-L-rknd

Ryoncil®

Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target 25 X 10<sup>6</sup>/ 3.8mL (6.68 x 10<sup>6</sup>/mL)

Kit for Patient Weight:

37.5 kg – <50 kg

Kit Contents:

1 X 4-vial carton

4 Alcohol Wipes



Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of 25 x 10<sup>6</sup> cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v (containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at ≤- 135°C; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

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U.S. License number: 2140



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EXP: MMMYYYY

PNTC-1154.027

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 73648-115-02

remestemcel-L-rknd

Ryoncil®

Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:

50 kg – <62.5 kg

Kit Contents:

1 X single vial carton

1 X 4-vial carton

5 Alcohol Wipes

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v

(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

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U.S. License number: 2140

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PNTC-1154.028

NDC 73648-115-02  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$ / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
50 kg – <62.5 kg

Kit Contents:  
1 X single vial carton  
1 X 4-vial carton  
5 Alcohol Wipes



Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

Manufactured for Mesoblast Inc.  
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New York, NY 10036  
U.S. License number: 2140



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PNTC-1154.028

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 73648-116-03  
remestemcel-L-rknd

Ryoncil®

Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6 / 3.8\text{mL}$  ( $6.68 \times 10^6/\text{mL}$ )

Kit for Patient Weight:

62.5 kg – <75 kg

Kit Contents:

2 X single vial cartons

1 X 4-vial carton

6 Alcohol Wipes

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v

(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

1114 Sixth Avenue, Fourth Floor

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U.S. License number: 2140

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SN: XXXXXXXXXXXXXXXX

LOT: XXXXXXXX

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PNTC-1154.029

NDC 73648-116-03

remestemcel-L-rknd

Ryoncil®

Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:

62.5 kg – <75 kg

Kit Contents:

2 X single vial cartons

1 X 4-vial carton

6 Alcohol Wipes



Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v (containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

1114 Sixth Avenue, Fourth Floor

New York, NY 10036

U.S. License number: 2140



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SN: XXXXXXXXXXXXX

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PNTC-1154.029

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 73648-117-04

remestemcel-L-rknd

Ryoncil®

Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:

75 kg – <87.5 kg

Kit Contents:

3 X single vial cartons

1 X 4-vial carton

7 Alcohol Wipes

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v

(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

1114 Sixth Avenue, Fourth Floor

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U.S. License number: 2140

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EXP: MMMYYYY

PNTC-1154.030

NDC 73648-117-04  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
75 kg – <87.5 kg

Kit Contents:  
3 X single vial cartons  
1 X 4-vial carton  
7 Alcohol Wipes



Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

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U.S. License number: 2140



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PNTC-1154.030

## PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 73648-118-02  
remestemcel-L-rknd

Ryoncil®

Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:

87.5 kg – <100 kg

Kit Contents:

2 X 4-vial cartons

8 Alcohol Wipes

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v

(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

1114 Sixth Avenue, Fourth Floor

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U.S. License number: 2140

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LOT: XXXXXXXX

EXP: MMMYYYY

PNTC-1154.031



NDC 73648-118-02  
remestemcel-L-rknd  
Ryoncil®

**Suspension for IV Infusion**

Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
87.5 kg – <100 kg

Kit Contents:  
2 X 4-vial cartons  
8 Alcohol Wipes



Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

Manufactured for Mesoblast Inc.  
1114 Sixth Avenue, Fourth Floor  
New York, NY 10036  
U.S. License number: 2140



GTIN: XXXXXXXXXXXXX  
SN: XXXXXXXXXXXXX  
LOT: XXXXXXXX  
EXP: MMMYYYY

PNTC-1154.031

**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL**

NDC 73648-119-03  
remestemcel-L-rknd

Ryoncil®

Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:

100 - < 112.5 kg

Kit Contents:

1 x Single vial carton

2 x 4-vial cartons

9 Alcohol wipes

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v

(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

1114 Sixth Avenue, Fourth Floor

New York, NY 10036

U.S. License number: 2140

GTIN: XXXXXXXXXXXXXXXX

SN: XXXXXXXXXXXXXXXX

LOT: XXXXXXXX

EXP: MMMYYYY

PNTC-1154.038

NDC 73648-119-03  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
100 - < 112.5 kg

Kit Contents:  
1 x Single vial carton  
2 x 4-vial cartons  
9 Alcohol wipes



Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

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New York, NY 10036  
U.S. License number: 2140



GTIN: XXXXXXXXXXXXX  
SN: XXXXXXXXXXXXX  
LOT: XXXXXXXX  
EXP: MMMYYYY

PNTC-1154.038

**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL**

NDC 73648-120-04

remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:

112.5 - < 125 kg

Kit Contents:

2 x Single vial carton

2 x 4-vial cartons

10 Alcohol wipes

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v

(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

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New York, NY 10036

U.S. License number: 2140

GTIN: XXXXXXXXXXXXXXXX

SN: XXXXXXXXXXXXXXXX

LOT: XXXXXXXX

EXP: MMMYYYY

PNTC-1154.039

NDC 73648-120-04  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
112.5 - < 125 kg

Kit Contents:  
2 x Single vial carton  
2 x 4-vial cartons  
10 Alcohol wipes



Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

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New York, NY 10036  
U.S. License number: 2140



GTIN: XXXXXXXXXXXXX  
SN: XXXXXXXXXXXXX  
LOT: XXXXXXXX  
EXP: MMMYYYY

PNTC-1154.039

NDC 73648-121-05  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
125 - < 137.5 kg

Kit Contents:  
3 x Single vial carton  
2 x 4-vial cartons  
11 Alcohol wipes

Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

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New York, NY 10036  
U.S. License number: 2140

GTIN: XXXXXXXXXXXXXXXX  
SN: XXXXXXXXXXXXXXXX  
LOT: XXXXXXXX  
EXP: MMMYYYY

PNTC-1154.040

NDC 73648-121-05  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$ / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
125 - < 137.5 kg

Kit Contents:  
3 x Single vial carton  
2 x 4-vial cartons  
11 Alcohol wipes



Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% w/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

Manufactured for Mesoblast Inc.  
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New York, NY 10036  
U.S. License number: 2140



GTIN: XXXXXXXXXXXXX  
SN: XXXXXXXXXXXXX  
LOT: XXXXXXXX  
EXP: MMMYYYY

PNTC-1154.040

**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL**

NDC 73648-122-03



remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion

Allogeneic bone marrow-derived mesenchymal stromal cells

Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:

137.5 - < 150 kg

Kit Contents:

3 x 4-vial cartons

12 Alcohol wipes

Single-use vial. Discard unused portion.

For intravenous administration after thaw and resuspension

Rx only

Sterile. No preservative.

See Prescribing Information for directions for use.

Complete infusion within 5 HOURS of thawing and resuspension of RYONCIL®.

Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.

Cryopreserved in: Human Serum Albumin Solution 20% v/v

(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 % v/v, dimethyl sulfoxide (DMSO) 10% v/v.

Contains known sensitizing substances DMSO or Porcine and Bovine proteins (see Prescribing Information, WARNINGS AND PRECAUTIONS).

Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen

No U.S. standard of potency.

Manufactured for Mesoblast Inc.

1114 Sixth Avenue, Fourth Floor

New York, NY 10036

U.S. License number: 2140

GTIN: XXXXXXXXXXXXXXXX

SN: XXXXXXXXXXXXXXXX

LOT: XXXXXXXX

EXP: MMMYYYY

PNTC-1154.041



NDC 73648-122-03  
remestemcel-L-rknd  
Ryoncil®

Suspension for IV Infusion  
Allogeneic bone marrow-derived mesenchymal stromal cells  
Target  $25 \times 10^6$  / 3.8mL ( $6.68 \times 10^6$ /mL)

Kit for Patient Weight:  
137.5 - < 150 kg

Kit Contents:  
3 x 4-vial cartons  
12 Alcohol wipes



Single-use vial. Discard unused portion.  
For intravenous administration after thaw and resuspension  
Rx only  
Sterile. No preservative.  
See Prescribing Information for directions for use.  
Complete infusion within 5 HOURS of thawing and resuspension  
of RYONCIL®.  
Each vial contains a target of  $25 \times 10^6$  cells / 3.8 mL.  
Cryopreserved in: Human Serum Albumin Solution 20% v/v  
(containing 5% w/v Human Serum Albumin), Plasma Lyte-A 70 %  
v/v, dimethyl sulfoxide (DMSO) 10% v/v.  
Contains known sensitizing substances DMSO or Porcine and  
Bovine proteins (see Prescribing Information, WARNINGS AND  
PRECAUTIONS).  
Store at  $\leq -135^\circ\text{C}$ ; vapor phase of liquid nitrogen  
No U.S. standard of potency.

Manufactured for Mesoblast Inc.  
1114 Sixth Avenue, Fourth Floor  
New York, NY 10036  
U.S. License number: 2140



GTIN: XXXXXXXXXXXXX  
SN: XXXXXXXXXXXXX  
LOT: XXXXXXXX  
EXP: MMMYYYY

PNTC-1154.041

**RYONCIL**

remestemcel-L-rknd kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73648-111

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73648-111-01	1 in 1 CARTON; Type 0: Not a Combination Product	03/17/2025	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, PLASTIC	3.8 mL
Part 2	1 POUCH	1 mL

Part 1 of 2
<b>RYONCIL</b> remestemcel-l-rknd suspension

Product Information	
Item Code (Source)	NDC:73648-154
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PLASMALYTE A (UNII: MZD2VV6EW6)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1		1 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

## Part 2 of 2

### ALCOHOL SWAB

isopropyl alcohol swab

## Product Information

Item Code (Source)	NDC:73648-155
Route of Administration	TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706	03/17/2025	

## RYONCIL

remestemcel-l-rknd kit

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73648-112
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73648-112-02	1 in 1 CARTON; Type 0: Not a Combination Product	03/17/2025	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 VIAL, PLASTIC	7.6 mL
Part 2	2 POUCH	2 mL

## Part 1 of 2

## RYONCIL

remestemcel-l-rknd suspension

### Product Information

Item Code (Source)	NDC:73648-154
Route of Administration	INTRAVENOUS

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
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PLASMALYTE A (UNII: MZD2VV6EW6)				
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)				
ALBUMIN HUMAN (UNII: ZIF514RVZR)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
2		1 in 1 CARTON		
2		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA		BLA125706		
Part 2 of 2				
ALCOHOL SWAB				
isopropyl alcohol swab				
Product Information				
Item Code (Source)		NDC:73648-155		
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)			ISOPROPYL ALCOHOL	0.7 mL in 1 mL
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	1 mL in 1 POUCH; Type 0: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706	03/17/2025	

RYONCIL				
remestemcel-l-rknd kit				
Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73648-113
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73648-113-03	1 in 1 CARTON; Type 0: Not a Combination Product	03/17/2025	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1	3 VIAL, PLASTIC		11.4 mL	
Part 2	3 POUCH		3 mL	
Part 1 of 2				
RYONCIL				
remestemcel-l-rknd suspension				
Product Information				
Item Code (Source)		NDC:73648-154		
Route of Administration		INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
PLASMALYTE A (UNII: MZD2VV6EW6)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
2		1 in 1 CARTON		
2		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
3		1 in 1 CARTON		
3		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

Part 2 of 2
ALCOHOL SWAB
isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:73648-155
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		

Ingredient Name		Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	0.7 mL in 1 mL	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M003		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA		BLA125706	03/17/2025	

RYONCIL				
remestemcel-l-rknd kit				
Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73648-114
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73648-114-01	1 in 1 CARTON; Type 0: Not a Combination Product	03/17/2025	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1	4 VIAL, PLASTIC		15.2 mL	
Part 2	4 POUCH		4 mL	



Part 1 of 2

RYONCIL

remestemcel-l-rknd suspension

Product Information

Item Code (Source)	NDC:73648-154
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PLASMALYTE A (UNII: MZD2VV6EW6)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

Part 2 of 2

ALCOHOL SWAB

isopropyl alcohol swab

Product Information				
Item Code (Source)		NDC:73648-155		
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)			ISOPROPYL ALCOHOL	0.7 mL in 1 mL
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M003		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA		BLA125706	03/17/2025	

RYONCIL				
remestemcel-l-rknd kit				
Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73648-115
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:73648-115-02	1 in 1 CARTON; Type 0: Not a Combination Product	03/17/2025	
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Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	5 VIAL, PLASTIC	19 mL
Part 2	5 POUCH	5 mL

Part 1 of 2

RYONCIL

remestemcel-l-rknd suspension

Product Information

Item Code (Source)	NDC:73648-154
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PLASMALYTE A (UNII: MZD2VV6EW6)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
2		4 in 1 CARTON		
2		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

Part 2 of 2

ALCOHOL SWAB

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:73648-155
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706	03/17/2025	

## remestemcel-l-rknd kit

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:73648-116
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73648-116-03	1 in 1 CARTON; Type 0: Not a Combination Product	03/17/2025	

Part #	Package Quantity	Total Product Quantity
Part 1	6 VIAL, PLASTIC	22.8 mL
Part 2	6 POUCH	6 mL

## remestemcel-l-rknd suspension

Item Code (Source)	NDC:73648-154
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<b>Route of Administration</b>	INTRAVENOUS
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Ingredient Name	Basis of Strength	Strength
<b>ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS</b> (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL

Ingredient Name	Strength
PLASMALYTE A (UNII: MZD2V6EW6)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
2		1 in 1 CARTON		
2		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
3		4 in 1 CARTON		
3		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

## Part 2 of 2

## ALCOHOL SWAB

isopropyl alcohol swab

## Product Information

Item Code (Source)	NDC:73648-155
Route of Administration	TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706	03/17/2025	

RYONCIL				
remestemcel-l-rknd kit				
Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	
			NDC:73648-117	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73648-117-04	1 in 1 CARTON; Type 0: Not a Combination Product	03/17/2025	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1	7 VIAL, PLASTIC		26.6 mL	
Part 2	7 POUCH		7 mL	
Part 1 of 2				
RYONCIL				
remestemcel-l-rknd suspension				
Product Information				
Item Code (Source)		NDC:73648-154		
Route of Administration		INTRAVENOUS		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength

<b>ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS</b> (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
<b>PLASMALYTE A</b> (UNII: MZD2VV6EW6)	
<b>DIMETHYL SULFOXIDE</b> (UNII: YOW8V9698H)	
<b>ALBUMIN HUMAN</b> (UNII: ZIF514RVZR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
2		1 in 1 CARTON		
2		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
3		1 in 1 CARTON		
3		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
4		4 in 1 CARTON		
4		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

Part 2 of 2

ALCOHOL SWAB

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:73648-155
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706	03/17/2025	

## RYONCIL

remestemcel-l-rknd kit

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:73648-118
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73648-118-02	1 in 1 CARTON; Type 0: Not a Combination Product	03/17/2025	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	8 VIAL, PLASTIC	30.4 mL
<b>Part 2</b>	8 POUCH	8 mL

Part 1 of 2

RYONCIL  
remestemcel-l-rknd suspension

Product Information

Item Code (Source)	NDC:73648-154
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PLASMALYTE A (UNII: MZD2VV6EW6)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
2		4 in 1 CARTON		
2		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

Part 2 of 2

ALCOHOL SWAB  
isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:73648-155
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706	03/17/2025	

RYONCIL			
remestemcel-l-rknd kit			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73648-119
Packaging			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73648-119-03	1 in 1 CARTON; Type 0: Not a Combination Product	09/28/2025	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1	9 VIAL, PLASTIC		34.2 mL	
Part 2	9 POUCH		9 mL	
Part 1 of 2				
RYONCIL				
remestemcel-l-rknd suspension				
Product Information				
Item Code (Source)		NDC:73648-154		
Route of Administration		INTRAVENOUS		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)			ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
PLASMALYTE A (UNII: MZD2VV6EW6)				
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)				
ALBUMIN HUMAN (UNII: ZIF514RVZR)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
2		4 in 1 CARTON		
2		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
3		4 in 1 CARTON		
3		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

Part 2 of 2

ALCOHOL SWAB

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:73648-155
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

BLA	BLA125706	09/28/2025	
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## RYONCIL

remestemcel-l-rknd kit

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73648-120
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73648-120-04	1 in 1 CARTON; Type 0: Not a Combination Product	09/28/2025	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	10 VIAL, PLASTIC	38 mL
Part 2	10 POUCH	10 mL

## Part 1 of 2

## RYONCIL

remestemcel-l-rknd suspension

### Product Information

Item Code (Source)	NDC:73648-154
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Route of Administration	INTRAVENOUS
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
PLASMALYTE A (UNII: MZD2VV6EW6)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
2		1 in 1 CARTON		
2		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
3		4 in 1 CARTON		
3		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
4		4 in 1 CARTON		
4		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

Part 2 of 2	
ALCOHOL SWAB	
isopropyl alcohol swab	

Product Information	
Item Code (Source)	NDC:73648-155
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name		Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		0.7 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M003		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA		BLA125706	09/28/2025	

RYONCIL				
remestemcel-l-rknd kit				
Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	
			NDC:73648-121	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73648-121-05	1 in 1 CARTON; Type 0: Not a Combination Product	09/28/2025	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1	11 VIAL, PLASTIC		41.8 mL	
Part 2	11 POUCH		11 mL	
Part 1 of 2				
RYONCIL				
remestemcel-l-rknd suspension				
Product Information				



<b>Item Code (Source)</b>	NDC:73648-154
<b>Route of Administration</b>	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS</b> (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
<b>PLASMALYTE A</b> (UNII: MZD2VV6EW6)	
<b>DIMETHYL SULFOXIDE</b> (UNII: YOW8V9698H)	
<b>ALBUMIN HUMAN</b> (UNII: ZIF514RVZR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
2		1 in 1 CARTON		
2		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
3		1 in 1 CARTON		
3		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
4		4 in 1 CARTON		
4		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
5		4 in 1 CARTON		
5		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

Part 2 of 2

<b>ALCOHOL SWAB</b> isopropyl alcohol swab
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Product Information	
Item Code (Source)	NDC:73648-155
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706	09/28/2025	

RYONCIL				
remestemcel-l-rknd kit				
Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:73648-122
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:73648-122-03	1 in 1 CARTON; Type 0: Not a Combination Product	09/28/2025	
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**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	12 VIAL, PLASTIC	45.6 mL
Part 2	12 POUCH	12 mL

**Part 1 of 2**

**RYONCIL**

remestemcel-l-rknd suspension

**Product Information**

Item Code (Source)	NDC:73648-154
Route of Administration	INTRAVENOUS

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS (UNII: OEN4982XNW) (ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS - UNII:OEN4982XNW)	ALLOGENIC BONE-MARROW-DERIVED MESENCHYMAL STEM CELLS	6680000 [arb'U] in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
PLASMALYTE A (UNII: MZD2VV6EW6)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ALBUMIN HUMAN (UNII: ZIF514RVZR)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 in 1 CARTON		
1		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
2		4 in 1 CARTON		
2		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		
3		4 in 1 CARTON		
3		3.8 mL in 1 VIAL, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706		

Part 2 of 2

ALCOHOL SWAB

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:73648-155
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125706	09/28/2025	

## Labeler - Mesoblast (616697426)

### Establishment

Name	Address	ID/FEI	Business Operations
Mesoblast, Inc.		616697426	manufacture(73648-154, 73648-111, 73648-112, 73648-113, 73648-114, 73648-115, 73648-116, 73648-117, 73648-118, 73648-119, 73648-120, 73648-121, 73648-122)

### Establishment

Name	Address	ID/FEI	Business Operations
LONZA BIOLOGICS TUAS PTE. LTD.		936939342	manufacture(73648-154) , analysis(73648-154) , label(73648-154) , pack(73648-154)

### Establishment

Name	Address	ID/FEI	Business Operations
Integrated Commercialization Solutions, LLC		832820588	pack(73648-154, 73648-111, 73648-112, 73648-113, 73648-114, 73648-115, 73648-116, 73648-117, 73648-118, 73648-119, 73648-120, 73648-121, 73648-122)

### Establishment

Name	Address	ID/FEI	Business Operations
WuXi Advanced Therapies Inc.		117556312	analysis(73648-154)

Revised: 9/2025

Mesoblast