ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

mRESVIA dispersion for injection in pre-filled syringe
Respiratory Syncytial Virus mRNA vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single-dose pre-filled syringe contains one dose of 0.5 mL.

One dose (0.5 mL) contains 50 micrograms of Respiratory Syncytial Virus (RSV) mRNA vaccine (nucleoside modified) encapsulated in lipid nanoparticles.

The active substance is a single-stranded 5' capped mRNA encoding the RSV-A glycoprotein F stabilised in the prefusion conformation.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Dispersion for injection.
White to off-white dispersion (pH: 7.0 – 8.0).

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

mRESVIA is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus in adults 60 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

4.2 Posology and method of administration

Posology

The recommended dose of mRESVIA is one single dose of 0.5 mL.

Paediatric population
The safety and efficacy of mRESVIA in children (from birth to less than 18 years of age) have not yet been established. No data are available.

Method of administration

For intramuscular injection only.

mRESVIA should be administered preferably in the deltoid muscle of the upper arm. The injection should be given using standard aseptic technique.

The vaccine must not be injected intravenously, subcutaneously or intradermally.

The vaccine should not be mixed with any other vaccines or medicinal products in the same syringe.

For instructions for preparation of the medicinal product before administration and special handling requirements, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Hypersensitivity and anaphylaxis

Appropriate medical treatment and supervision should always be readily available in case of a severe hypersensitivity reaction, including anaphylaxis, following administration of the vaccine.

Anxiety-related reactions

Anxiety-related reactions including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute infection or febrile illness. The presence of a minor infection, such as a cold, should not delay vaccination.

Thrombocytopenia and coagulation disorders

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

Safety and immunogenicity data on mRESVIA are not available for immunocompromised individuals. Individuals receiving immunosuppressant therapy or patients with immunodeficiency may have a diminished immune response to this vaccine.

Limitations of vaccine effectiveness

As with all vaccines, vaccination with mRESVIA may not protect all vaccine recipients.

Excipient - sodium

This vaccine contains less than 1 mmol sodium (23 mg) per 0.5 mL dose, that is to say essentially ‘sodium-free.’

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies with other medicinal products have been performed.

Concomitant administration of mRESVIA with other vaccines has not been studied.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

This vaccine is not indicated in women of childbearing potential (see section 4.1). It is not to be used in women who are or may be pregnant or breast-feeding.

Pregnancy

There are no or limited amount of data from the use of mRESVIA in pregnant women. Animal studies with mRESVIA do not indicate direct or indirect harmful effects with respect to pregnancy (see section 5.3).

Breast-feeding

It is unknown whether mRESVIA is excreted in human milk.

Fertility

No human data on the effect of mRESVIA on fertility are available.

Animal studies with mRESVIA do not indicate direct or indirect harmful effects with respect to female reproductive toxicity. Animal studies are insufficient to assess male reproductive toxicity (see section 5.3).

4.7 Effects on ability to drive and use machines

mRESVIA has no or negligible influence on the ability to drive and use machines.

However, some of the effects mentioned under section 4.8 (e.g., fatigue, dizziness) may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions were injection site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (26.6%) and arthralgia (21.7%). The onset of most solicited local and systemic adverse reactions was within 1 to 2 days after injection and resolved within 1 to 2 days after onset. The majority of local and systemic solicited adverse reactions were mild in intensity.

Tabulated list of adverse reactions

The safety profile and the frequencies of adverse reactions presented below are based on data generated in a global placebo-controlled phase 2/3 clinical study (EUDRA CT number 2021-005026-20) with a total of 18 245 participants aged ≥ 60 years who received one injection of 50 micrograms of mRESVIA. The clinical study was conducted in 22 countries in Central and Latin America, Africa, Asia Pacific, North America and Europe.

For information on the main characteristics of the patient population in the phase 2/3 clinical study, see section 5.1.

Adverse reactions reported are listed according to the following frequency convention:

Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1 000 to < 1/100)
Rare (≥ 1/10 000 to < 1/1 000)
Very rare (< 1/10 000)

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness (Table 1).

Table 1: Adverse reactions following administration of mRESVIA

MedDRA system organ class	**Frequency**	**Adverse reaction(s)**
Blood and lymphatic system disorders	Very common	Lymphadenopathy[*]
Immune system disorders	Uncommon	Hypersensitivity
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness
	Rare	Peripheral facial nerve paralysis (e.g., Bell's palsy)[†]
Gastrointestinal disorders	Common	Nausea/vomiting
Skin and subcutaneous tissue disorders	Rare	Urticaria[‡]
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills
	Common	Pyrexia Injection site erythema Injection site swelling/induration
	Rare	Injection site pruritus

[*] Lymphadenopathy was collected as "Axillary (underarm) swelling or tenderness ipsilateral to the side of injection".
[†] One participant in the vaccine group had a serious adverse event of facial paralysis with onset on Day 5 assessed by the investigator as related to injection. Within the 42-day risk window following injection, Bell's palsy and/or facial paralysis was reported by 2 participants in the mRESVIA group and 2 participants in the placebo group. All 4 of these participants had risk factors for Bell's palsy.
[‡] Urticaria has been observed with either acute onset (within a few days after vaccination) or delayed onset (up to approximately two weeks after vaccination) and may be acute or chronic (≥ 6 weeks) in duration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Overdose with mRESVIA is unlikely due to its single dose presentation (see section 4.2).

In case of overdose, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vaccine, other viral vaccines, ATC code: J07BX05

Mechanism of action

mRESVIA is an mRNA-based vaccine encoding the membrane-anchored RSV-A F glycoprotein stabilised in the prefusion conformation through changes to the amino acid sequence. The RSV-A prefusion glycoprotein is antigenically cross-reactive to the RSV-B prefusion glycoprotein. The prefusion F glycoprotein is the target of neutralising antibodies that mediate protection against RSV-associated respiratory tract disease.

mRESVIA stimulates production of RSV-A and RSV-B neutralising antibodies and induction of antigen-specific cellular immune responses.

Clinical efficacy and safety

Study EUDRA CT number 2021-005026-20 is an ongoing phase 2/3 randomised, observer-blind, placebo-controlled, case-driven pivotal study that was conducted in 22 countries. This study evaluated the safety and efficacy of a single dose of mRESVIA (50 micrograms) to prevent RSV-LRTD in adults ≥ 60 years with or without underlying medical conditions for up to a year after single vaccination with mRESVIA. Participants were randomised in a 1:1 ratio to mRESVIA or placebo. Randomisation was stratified by age and comorbidities increasing the risk of severe LRTD (see Table 2 and related footnotes).

The primary efficacy analysis population (referred to as the per-protocol efficacy set), included 35 088 participants who received either mRESVIA (n=17 572) or placebo (n=17 516). Most participants were White (63.5%); 12.2% of participants were Black or African American, 8.7% were Asian, and 15.2% reported 'Other'. A total of 34.6% of participants were Hispanic or Latino. Treatment groups were balanced according to race and ethnicity. Risk factors were balanced between treatment groups.

There were approximately the same number of male and female participants (male 50.9%; female 49.1%). The median age of participants was 67.0 years (range: 60 to 96 years), with 63.5% of participants between 60-69 years, 30.9% of participants between 70 and 79 years and 5.5% of participants ≥ 80 years. There were no notable differences in demographics or pre-existing medical conditions between participants who received mRESVIA and those who received placebo. A total of 6.9% had protocol-defined LRTD risk factors [congestive heart failure (CHF) and/or chronic obstructive pulmonary disease (COPD)] and 29.3% had one or more comorbidity of interest (see

Table 2 and related footnotes). A total of 21.8% of the per-protocol efficacy set scored “vulnerable” or “frail” according to Edmonton Frail Scale.

The primary efficacy endpoints were the prevention of a first episode of RSV-associated lower respiratory tract disease (RSV-LRTD) with ≥ 2 or ≥ 3 symptoms between 14 days and 12 months post injection. RSV-LRTD was defined by the following criteria: the participant must have had reverse transcription polymerase chain reaction(RT-PCR)-confirmed RSV infection and radiologic evidence of pneumonia or experienced new or worsening of at least 2 or more (or 3 or more) of the following symptoms, lasting for at least 24 hours: shortness of breath, cough and/or fever (≥ 37.8 °C), wheezing and/or rales and/or rhonchi, sputum production, tachypnoea (≥ 20 breaths per minute or increase of ≥ 2 breaths per minute from baseline measurement in those who have baseline tachypnoea), hypoxemia (new onset oxygen saturation ≤ 93% or increasing use of supplemental oxygen), pleuritic chest pain.

The primary efficacy endpoints have been met (lower bound of the alpha-adjusted confidence interval [CI] of the vaccine efficacy [VE] was > 20%), including VE of 83.7% (95.88% CI: 66.0%, 92.2%; p< 0.0001) against RSV-LRTD as defined by two or more symptoms. The other primary efficacy endpoint against RSV-LRTD defined by three or more symptoms was also met, with a VE of 82.4% (96.36% CI: 34.8%, 95.3%; p=0.0078). These analyses were performed after a median of 3.7 months of follow-up. An additional analysis of efficacy was performed after a median of 8.6 months of follow-up (range 15 to 530 days). A single dose of mRESVIA met the same criterion as defined in the primary analysis for the prevention of RSV-LRTD (lower bound of the 95% CI of the VE was > 20%). Vaccine efficacy in adults ≥ 60 years against RSV-LRTD with 2 or more signs/symptoms was 63.3% (95% CI: 48.7%, 73.7%; number of participants in mRESVIA group was n=47 / N=18 112 and in the placebo group was n=127 / N= 18 045) and against RSV-LRTD with 3 or more signs/symptoms was 63.0% (95% CI: 37.3%, 78.2%; number of participants in mRESVIA group was n=19 / N=18 112 and in the placebo group was n=51 / N=18 045).

At the time of the additional analysis (median follow up 8.6 months, range 0.5-17.7 months), point estimates of VE in the subgroup analyses by age, comorbidity and frailty were generally consistent with VE of overall population based on the PPE Set (Table 2).

Table 2: Additional analysis of vaccine efficacy (VE) of mRESVIA to prevent first episode of RSV-LRTD (with 2 or more symptoms) 14 days post-injection up to 12 months post-injection by subgroups (per-protocol efficacy set)

Subgroup	mRESVIA Cases, n/N*	Placebo Cases, n/N*	VE, % (95% CI)
Overall	47/18 112	127/18 045	63.3 (48.7, 73.7)
Age group			
60 to 69 years	31/11 219	77/11 170	60.1 (39.5, 73.7)
70 to 79 years	10/5 464	45/5 439	78.0 (56.3, 88.9)
≥ 80 years	6/1 429	5/1 436	NA†
Comorbidities‡			
None (0)	31/12 751	76/12 796	59.5 (38.5, 73.4)
One or more (≥ 1)	16/5 361	51/5 249	69.3 (46.1, 82.5)
Frailty status			
Fit (0-3)	37/13 417	104/13 274	65.0 (49.0, 75.9)
Vulnerable/Frailty (≥ 4)	9/3 817	17/3 884	46.5 (-20.0, 76.2)

* Based on the number of participants in each subgroup.
† NA = not applicable due to low number of total cases accrued in this subgroup.
‡ Comorbidities included in this analysis were chronic cardiopulmonary conditions, including CHF, COPD, asthma and chronic respiratory conditions as well as diabetes, advanced liver, and advanced kidney disease.

As shortness of breath is associated with more severe RSV disease, an exploratory analysis was conducted. A total of 54 cases of RSV-LRTD with shortness of breath occurred: 43 in placebo recipients and 11 in mRESVIA recipients.

Paediatric population

The European Medicines Agency has deferred the obligation to submit the results of studies with mRESVIA in one or more subsets of the paediatric population in prevention of Respiratory Syncytial Virus (RSV)-associated lower respiratory tract disease (LRTD), as per paediatric investigation plan (PIP) decision, for the granted indication (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazards for humans based on conventional studies of repeat toxicity, genotoxicity and developmental and reproductive toxicity.

General toxicity

General toxicity studies were conducted in rats (intramuscularly with mRESVIA receiving up to two doses that exceeded the human dose, once every 3 weeks or intramuscularly receiving up to

4-dose administrations of related vaccine drug products once every 2 weeks). Transient and reversible injection site oedema and erythema and transient and reversible changes in laboratory tests (including increases in eosinophils, activated partial thromboplastin time, and fibrinogen) were observed. Results suggests the toxicity potential to humans is low.

Genotoxicity/carcinogenicity

In vitro and *in vivo* genotoxicity studies were conducted to evaluate the novel lipid component SM-102 of the vaccine. Results suggests the genotoxicity potential to humans is very low. Carcinogenicity studies were not performed.

Developmental and reproductive toxicity

In a combined developmental and reproductive toxicity study, mRESVIA was administered to female rats 4 times intramuscularly at 96 micrograms/dose (twice prior to mating [28 and 14 days prior] and twice after mating [on gestation days 1 and 13]). Anti-RSV antibodies were present in maternal animals from prior to mating to the end of the study on lactation day 21, as well as in foetuses and offspring, and maternal milk. There were no vaccine-related adverse effects on female fertility, pregnancy, embryo foetal or offspring development or postnatal development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

SM-102 (Heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate)
Cholesterol
1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG)
Trometamol
Trometamol hydrochloride
Acetic acid
Sodium acetate trihydrate
Sucrose
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

1 year at -40 °C to -15 °C.

Within the shelf life of 1 year, stability data indicate that the vaccine is stable for 30 days when stored at 2 °C to 8 °C and protected from light. At the end of 30 days, the vaccine should be used immediately or discarded.

Once thawed, the vaccine should not be refrozen.

Upon moving the vaccine to 2 °C to 8 °C storage, the outer carton should be marked with the new expiry date at 2 °C to 8 °C.

If the vaccine is received at 2 °C to 8 °C, it should be stored at 2 °C to 8 °C. The expiry date on the outer carton should have been marked with the new expiry date at 2 °C to 8 °C.

The pre-filled syringes may be stored at 8 °C to 25 °C for up to 24 hours after removal from refrigerated conditions. Within this period of time, pre-filled syringes may be handled in ambient light conditions. Do not refrigerate after being stored at 8 °C to 25 °C. Discard the syringe if not used within this time.

6.4 Special precautions for storage

Store in a freezer at -40 °C to -15 °C.

Keep the pre-filled syringes in the original carton in order to protect from light.
For storage conditions after thawing of the vaccine, see section 6.3.

Transportation of thawed pre-filled syringes in the outer carton in liquid state at 2 °C to 8 °C
If transport at -40 °C to -15 °C is not feasible, available data support transportation of one or more thawed pre-filled syringes in liquid state at 2 °C to 8 °C (within the 30 days shelf life).
Once thawed and transported in liquid state at 2 °C to 8 °C, pre-filled syringes should not be refrozen and should be stored at 2 °C to 8 °C until use (see section 6.3).

6.5 Nature and contents of container

0.5 mL dispersion in a pre-filled syringe (polymeric barrel) with plunger stopper and a rubber tip cap (without needle).

The pre-filled syringe is packaged within a carton in either a tray containing 1 or 10 pre-filled syringes, in 1 clear blister containing 1 pre-filled syringe or in 5 clear blisters containing 2 pre-filled syringes in each blister.

Pack sizes:
10 pre-filled syringes per carton
1 pre-filled syringe per carton
Each pre-filled syringe contains 0.5 mL.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

This vaccine should be administered by a trained healthcare professional using aseptic techniques to ensure sterility.

Handling instructions for mRESVIA before use

The vaccine is ready to use once thawed.

Do not dilute the product.

Do not shake the pre-filled syringe before use.

The pre-filled syringe is for single-use only.

Do not use if the pre-filled syringe has been dropped or damaged or the security seal on the carton has been broken.

mRESVIA is shipped and supplied either as a frozen or thawed pre-filled syringe (see section 6.4). If the vaccine is frozen, it must be completely thawed before use. Thaw each pre-filled syringe before use, either in the refrigerator or at room temperature, following the instructions in Table 3.

Prior to immediate use, single blisters or pre-filled syringes may be removed from a carton of 1 or 10 pre-filled syringes and thawed either in the refrigerator or at room temperature. The remaining blisters or syringes must continue to be stored in their original carton in the freezer or refrigerator.

Table 3: Thawing conditions and times based on pack size and temperature before use

Pack size	Thaw instructions and durations			
	Thaw temperature (in refrigerator) (°C)	**Thaw duration (minutes)**	**Thaw temperature (at room temperature) (°C)**	**Thaw duration (minutes)**
Carton of 1 pre-filled syringe	2 - 8	100	15 - 25	40
Carton of 10 pre-filled syringes	2 - 8	160	15 - 25	80
1 pre-filled syringe (removed from carton)	2 - 8	100	15 - 25	40

- After thawing, the vaccine cannot be refrozen.
- If the vaccine has been thawed at room temperature (15 °C to 25 °C), the pre-filled syringe is ready to administer. Syringes should not be returned to the refrigerator after being thawed at room temperature.
- The pre-filled syringes may be stored at 8 °C to 25 °C for a total of 24 hours after removal from refrigerated conditions. Within this period of time, pre-filled syringes may be handled in ambient light conditions. Discard the syringe if not used within this time.

Administration

- Remove a pre-filled syringe from the blister or tray.
- The vaccine should be inspected visually for particulate matter and discolouration prior to administration. mRESVIA is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discoloured or contains other particulate matter.
- With tip cap upright, remove tip cap by twisting counter-clockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.
- The vaccine should be administered immediately after uncapping.
- Needles are not provided in the pack.
- Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner needles).
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the pre-filled syringe.
- Administer the entire dose intramuscularly.
- Discard the pre-filled syringe after use.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MODERNA BIOTECH SPAIN, S.L.
C/ Julián Camarillo nº 31
28037 Madrid
Spain

8. MARKETING AUTHORISATION NUMBERS

EU/1/24/1849/001
EU/1/24/1849/002
EU/1/24/1849/003
EU/1/24/1849/004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 August 2024

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency https://www.ema.europa.eu.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

ModernaTX, Inc.
One Moderna Way
Norwood, MA 02062
USA

Name and address of the manufacturer responsible for batch release

MODERNA BIOTECH SPAIN, S.L
C/ Julián Camarillo n° 31
28037 Madrid
Spain

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

- **Official batch release**

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European Medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

mRESVIA dispersion for injection in pre-filled syringe
Respiratory Syncytial Virus mRNA vaccine

2. STATEMENT OF ACTIVE SUBSTANCE

Each single dose pre-filled syringe contains 0.5 mL. One dose (0.5 mL) contains 50 micrograms of Respiratory Syncytial Virus mRNA.

3. LIST OF EXCIPIENTS

Excipients: SM-102 (Heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino)octanoate), cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose and water for injections.

See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Dispersion for injection
1 pre-filled syringe
10 pre-filled syringes

5. METHOD AND ROUTE OF ADMINISTRATION

For single use only.
Read the package leaflet before use.
Intramuscular use.

QR code to be included

Scan here or visit www.mresvia.eu.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP (-40 °C to -15 °C)
EXP (2 °C to 8 °C)

9. SPECIAL STORAGE CONDITIONS

Store in a freezer (-40 °C to -15 °C).

For additional information on shelf-life and storage, see package leaflet.
Keep the pre-filled syringe in the outer carton in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Dispose of in accordance with local requirement.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MODERNA BIOTECH SPAIN, S.L.
C/ Julián Camarillo nº 31
28037 Madrid
Spain

12. MARKETING AUTHORISATION NUMBERS

EU/1/24/1849/001 (blister pack of 1)
EU/1/24/1849/002 (blister pack of 10)
EU/1/24/1849/003 (tray of 1)
EU/1/24/1849/004 (tray 0f 10)

13. BATCH NUMBER, DONATION AND PRODUCT CODES

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PRE-FILLED SYRINGE LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE OF ADMINISTRATION

mRESVIA dispersion for injection
RSV mRNA vaccine
IM

2. METHOD OF ADMINISTRATION

Intramuscular use

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

0.5 mL

6. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

mRESVIA dispersion for injection
Respiratory Syncytial Virus mRNA vaccine

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What mRESVIA is and what it is used for

mRESVIA is a vaccine that helps to protect adults aged 60 years and older against a virus called 'respiratory syncytial virus' (RSV).

RSV is a common virus that spreads very easily and causes respiratory tract disease in people of all ages. RSV infection can be mild, with cold-like symptoms including blocked nose, cough and/or sore throat. However, the virus can also cause more serious problems, such as lung infections and pneumonia. Older adults are at risk of more serious complications that can lead to hospital admission or even death.

mRESVIA activates the immune system (the body's natural defences) to protect against lung diseases caused by the RSV. The vaccine contains a substance called messenger ribonucleic acid (mRNA) that contains instructions that the body can use to make the same protein present on the RSV. When the immune system encounters this protein, it makes antibodies (substances in the blood that recognise and fight infections) against it. If a person comes into contact with the RSV, the immune system will recognise and attack the virus to help protect you against lung diseases caused by it.

2. What you need to know before you receive mRESVIA

Do not use mRESVIA
- if you are allergic to the active substance or any of the ingredients of this vaccine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given mRESVIA if:

- you have ever had a severe allergic reaction after any other vaccine injection in the past.
- you have a bleeding problem or bruise easily.

- you have a weakened immune system which may prevent you from getting the full benefit from mRESVIA.
- you are feeling nervous about getting the vaccine or have ever fainted after any injection.
- you have an infection with a high fever. If this is the case, then vaccination will be postponed. There is no need to delay vaccination for a minor infection, such as a cold, but talk to your doctor first.

As with all vaccines, mRESVIA may not fully protect all people who are vaccinated.

Children and adolescents
mRESVIA is not indicated for use in children and adolescents below the age of 18 years.

Other medicines and mRESVIA
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
The vaccine should not be used in women who are of childbearing potential, pregnant or breast feeding.

Driving and using machines
Some of the effects mentioned below in section 4 “Possible side effects” like feeling tired and dizziness may temporarily affect the ability to drive or use machines. If you experience such side effects, wait until they have worn off before you drive or use machines.

mRESVIA contains sodium
This vaccine contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially ‘sodium-free.’

3. How and when mRESVIA is given

mRESVIA is given by a doctor, pharmacist or nurse, usually as a single injection in the muscle of the upper arm (deltoid muscle).

The recommended dose is 0.5 mL.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Side effects that may happen after receiving mRESVIA include:

Very common (may affect more than 1 in 10 people)
- swelling/tenderness in the underarm (lymphadenopathy)
- headache
- muscle ache (myalgia)
- joint ache (arthralgia)
- pain at the injection site
- feeling tired (fatigue)
- chills

Common (may affect up to 1 in 10 people)
- feeling sick (nausea)/vomiting

- redness (erythema) at the injection site
- swelling/hardening (induration) at the injection site
- fever (pyrexia)

Uncommon (may affect up to 1 in 100 people)
- reaction of increased sensitivity or intolerance by the immune system (hypersensitivity)
- dizziness

Rare (may affect up to 1 in 1 000 people)
- temporary one-sided facial drooping (Bell`s palsy)
- itchy rash (urticaria)
- itching at the injection site (pruritus)

Tell your doctor or pharmacist if you get any of the side effects listed above. Most of these side effects are mild to moderate in intensity and do not last long.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this vaccine.

5. How to store mRESVIA

Your doctor, pharmacist or nurse is responsible for storing this vaccine and disposing of any unused product correctly. The following information is intended for healthcare professionals.

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Frozen vaccine
Store in a freezer between -40 °C to -15 °C.

Keep the pre-filled syringes in the original carton in order to protect from light.

Within the shelf life of 1 year, stability data indicate that the vaccine is stable for 30 days when stored at 2 °C to 8 °C and protected from light. At the end of 30 days, the vaccine should be used immediately or discarded.

Once thawed, the vaccine should not be refrozen.

Upon moving the vaccine to 2 °C to 8 °C storage, the outer carton should be marked with the new expiry date at 2 °C to 8 °C.

If the vaccine is received at 2 °C to 8 °C, it should be stored at 2 °C to 8 °C. The expiry date on the outer carton should have been marked with the new expiry date at 2 °C to 8 °C.

The pre-filled syringes may be stored at 8 °C to 25 °C for up to 24 hours after removal from the refrigerated conditions. Within this period of time, pre-filled syringes may be handled in ambient light conditions. Do not refrigerate after being stored at 8 °C to 25 °C. Discard the syringe if not used within this time.

Transportation of thawed pre-filled syringes in the outer carton in liquid state at 2 °C to 8 °C
If transport at -40 °C to -15 °C is not feasible, available data support transportation of one or more thawed pre-filled syringes in liquid state at 2 °C to 8 °C (within the 30 days shelf life).
Once thawed and transported in liquid state at 2 °C to 8 °C, pre-filled syringes should not be refrozen and should be stored at 2 °C to 8 °C until use.

6. Contents of the pack and other information

What mRESVIA contains

One pre-filled syringe of 0.5 mL contains 50 micrograms of Respiratory Syncytial Virus (RSV) mRNA vaccine (nucleoside modified) encapsulated in lipid nanoparticles.

The active substance is a single-stranded 5’ capped mRNA encoding the Respiratory Syncytial Virus glycoprotein F stabilised in the prefusion conformation.

The other excipients are SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino)octanoate), cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose and water for injections.

See Section 2 “mRESVIA contains sodium”.

What mRESVIA looks like and contents of the pack

mRESVIA is a white to off-white dispersion for injection (pH: 7.0 – 8.0).

mRESVIA is available in packs containing 1 or 10 pre-filled syringes.

Not all pack sizes may be marketed.

Needles are not provided in the pack.

Marketing Authorisation Holder and Manufacturer
MODERNA BIOTECH SPAIN, S.L.
C/ Julián Camarillo nº 31
28037 Madrid
Spain

For any information about this vaccine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
Tél/Tel: 0800 81 460

България
Тел: 0800 115 4477

Česká republika
Tel: 800 050 719

Danmark
Tlf.: 80 81 06 53

Deutschland

Lietuva
Tel: 88 003 1114

Luxembourg/Luxemburg
Tél/Tel: 800 85 499

Magyarország
Tel: 06 809 87488

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Tel: 08009614

Ireland
Tel: 1800 800 354

Ísland
Sími: 800 4382

Italia
Tel: 800 928 007

Κύπρος
Τηλ: 80091080

Latvija
Tel: 80 005 898

Tel: 0800 409 0001

Norge
Tlf: 800 31 401

Österreich
Tel: 0800 909636

Polska
Tel: 800 702 406

Portugal
Tel: 800 210 256

România
Tel: 0800 400 625

Slovenija
Tel: 080 083082

Slovenská republika
Tel: 0800 191 647

Suomi/Finland
Puh/Tel: 0800 774198

Sverige
Tel: 020 10 92 13

This leaflet was last revised in

Other sources of information

Scan the QR code with a mobile device to get the package leaflet in different languages or visit www.mresvia.eu.

QR code to be included

Detailed information on this vaccine is available on the European Medicines Agency web site: https://www.ema.europa.eu.

The following information is intended for healthcare professionals only:

This vaccine should be administered by a trained healthcare professional using aseptic techniques to ensure sterility.

Handling instructions for mRESVIA before use

The vaccine is ready to use once thawed.

Do not dilute the product.

Do not shake the pre-filled syringe before use.

The pre-filled syringe is for single-use only.

Do not use if the pre-filled syringe has been dropped or damaged or the security seal on the carton has been broken.

mRESVIA is shipped and supplied either as a frozen or thawed pre-filled syringe (see section 5). If the vaccine is frozen, it must be completely thawed before use. Thaw each pre-filled syringe before use, either in the refrigerator or at room temperature, following the instructions in Table 1.

Prior to immediate use, single blisters or pre-filled syringes may be removed from a carton of 1 or 10 pre-filled syringes and thawed either in the refrigerator or at room temperature. The remaining blisters or syringes must continue to be stored in their original carton in the freezer or refrigerator.

Table 1: Thawing conditions and times based on pack size and temperature before use

Pack size	**Thaw instructions and durations**			
	Thaw temperature (in refrigerator) (°C)	**Thaw duration (minutes)**	**Thaw temperature (at room temperature) (°C)**	**Thaw duration (minutes)**
Carton of 1 pre-filled syringe	2 - 8	100	15 - 25	40
Carton of 10 pre-filled syringes	2 - 8	160	15 - 25	80
1 pre-filled syringe (removed from carton)	2 - 8	100	15 - 25	40

- After thawing, the vaccine cannot be refrozen.
- If the vaccine has been thawed at room temperature (15 °C to 25 °C), the pre-filled syringe is ready to administer.
- Syringes should not be returned to the refrigerator after being thawed at room temperature.
- The pre-filled syringes may be stored at 8 °C to 25 °C for a total of 24 hours after removal from refrigerated conditions. Within this period of time, pre-filled syringes may be handled in ambient light conditions. Discard the syringe if not used within this time.

Administration
- Remove a pre-filled syringe from the blister or tray.
- The vaccine should be inspected visually for particulate matter and discolouration prior to administration. mRESVIA is a white to off-white dispersion. It may contain white or translucent product-related particulates. Do not administer if vaccine is discoloured or contains other particulate matter.
- With tip cap upright, remove tip cap by twisting counter-clockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.
- The vaccine should be administered immediately after uncapping.
- Needles are not provided in the pack.

- Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner needles).
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the pre-filled syringe.
- Administer the entire dose intramuscularly.
- Discard the pre-filled syringe after use.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.