

ROMIDEPSIN-REACH

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ROMIDEPSIN-REACH?

ROMIDEPSIN-REACH is used to treat a type of cancer called peripheral T-cell lymphoma, or PTCL, in patients who have received at least one previous treatment for this condition.

For more information, see Section [1. Why am I using ROMIDEPSIN-REACH?](#) in the full CMI.

2. What should I know before I use ROMIDEPSIN-REACH?

Do not use if you have ever had an allergic reaction to romidepsin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ROMIDEPSIN-REACH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ROMIDEPSIN-REACH and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ROMIDEPSIN-REACH?

- ROMIDEPSIN-REACH will be given to you as an intravenous (IV) infusion into your vein by your doctor or nurse.
- Your doctor will choose the correct dose for you depending on your height, weight and blood test results.

More instructions can be found in Section [4. How do I use ROMIDEPSIN-REACH?](#) in the full CMI.

5. What should I know while using ROMIDEPSIN-REACH?

Things you should do	<ul style="list-style-type: none">• If you become pregnant while being given ROMIDEPSIN-REACH, tell your doctor immediately.• Tell all doctors, dentists, and pharmacists who treat you that you are being given this medicine.• If you are going to have surgery, tell the surgeon or anaesthetist that you are being given ROMIDEPSIN-REACH. It may affect other medicines used during or after the surgery.• Drink plenty of fluids while taking ROMIDEPSIN-REACH. Discuss with your doctor how much water you should drink.• Having enough fluids may help to reduce the chances of dehydration.• Keep all of your doctor's appointments so that your progress can be checked.• Your doctor will need to perform regular ECG (heart function) tests and blood tests.
Driving or using machines	Be careful driving or operating machinery until you know how it affects you. This medicine may cause tiredness or the feeling of weakness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

For more information, see Section [5. What should I know while using ROMIDEPSIN-REACH?](#) in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ROMIDEPSIN-REACH

Active ingredient(s): *romidepsin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ROMIDEPSIN-REACH. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ROMIDEPSIN-REACH.**

Where to find information in this leaflet:

- [1. Why am I using ROMIDEPSIN-REACH?](#)
- [2. What should I know before I use ROMIDEPSIN-REACH?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ROMIDEPSIN-REACH?](#)
- [5. What should I know while using ROMIDEPSIN-REACH?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ROMIDEPSIN-REACH?

ROMIDEPSIN-REACH contains an active ingredient called romidepsin. ROMIDEPSIN-REACH anti-cancer (antineoplastic) medicine that belongs to a group of medicines known as histone deacetylase or HDAC inhibitors. ROMIDEPSIN-REACH is used to treat a type of cancer called peripheral T-cell lymphoma, or PTCL, in patients who have received at least one previous treatment for this condition.

2. What should I know before I use ROMIDEPSIN-REACH?

Warnings

Do not use ROMIDEPSIN-REACH if:

- you are allergic to romidepsin, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

- rash, itching or hives on the skin.

Check with your doctor if you:

- have any other medical conditions
- **you have a history of heart problems or are taking medicines used to help treat abnormal rhythms of the heart (anti-arrhythmics).**

ROMIDEPSIN-REACH treatment has been associated with the occurrence of abnormal heart rhythms.

Your doctor may conduct a heart function (electrocardiograph [ECG]) test before and during treatment to monitor the activity of your heart

- **you have a history of blood conditions which affect the number of blood cells in your body.**

This medicine can cause a reduction in the numbers of blood cells. Your doctor will ask you to take regular blood tests to monitor the levels of your blood cells.

- **you have a history of frequent infections, or a history of hepatitis B or Epstein Barr virus infection.**

This medicine can cause a reduction in the numbers of blood cells used by the body to fight infection. Your doctor will ask you to take regular blood tests to monitor the levels of your blood cells.

- **you have a history of liver problems.**

Your doctor may adjust the dose of the medicine depending on the severity of your liver condition.

- **you have a history of kidney problems.**
- **you have problems with the amount of potassium or magnesium in your blood.**
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

ROMIDEPSIN-REACH can harm your unborn baby. Your doctor will ask you to have a pregnancy test prior to

starting treatment with ROMIDEPSIN-REACH. Your doctor can discuss with you the risks and benefits of using this medicine during pregnancy.

- **use reliable means of contraception during treatment and treatment interruption, and for at least 4 weeks after ROMIDEPSIN-REACH treatment has stopped.**

Your doctor will tell you what method of contraception to use.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if ROMIDEPSIN-REACH passes into breast milk. Your doctor will help to decide if you should stop breast-feeding when you start treatment with this medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ROMIDEPSIN-REACH and affect how it works. These are:

- warfarin or any other blood thinner used to prevent blood clots
- medicines used to treat heart problems such as arrhythmia (irregular beating of the heart)
- medicines used to treat fungal infections (such as ketoconazole)
- medicines used to treat tuberculosis (such as rifampicin)
- oestrogen-containing oral contraceptive pills for women
- St John's Wort.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have a more complete list of medicines to be careful with or avoid while taking ROMIDEPSIN-REACH.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ROMIDEPSIN-REACH.

4. How do I use ROMIDEPSIN-REACH?

How much to take / use

ROMIDEPSIN-REACH will be given to you as an intravenous (IV) infusion into your vein by your doctor or nurse.

Your doctor will choose the correct dose of ROMIDEPSIN-REACH for you.

- Your dose will depend on your general condition and your height and weight.
- Your dose will be calculated based on your body surface area, with the usual dose of 14 mg ROMIDEPSIN-REACH per metre squared of body surface area.
- ROMIDEPSIN-REACH will be given to you over a 4-hour period on Days 1, 8 and 15 of a 28-day cycle. These cycles may be repeated for as long as you continue to receive benefit from ROMIDEPSIN-REACH.
- Your doctor will check your progress and may change your dose if necessary.

5. What should I know while using ROMIDEPSIN-REACH?

Things you should do

If you become pregnant while being given ROMIDEPSIN-REACH, tell your doctor immediately.

Tell all doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given ROMIDEPSIN-REACH.

It may affect other medicines used during or after the surgery.

Drink plenty of fluids while taking ROMIDEPSIN-REACH. Discuss with your doctor how much water you should drink.

Having enough fluids may help to reduce the chances of dehydration.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will need to perform regular ECG (heart function) tests and blood tests.

Remind any doctor, dentist or pharmacist you visit that you are using ROMIDEPSIN-REACH.

Driving or using machines

Be careful driving or operating machinery until you know how it affects you.

ROMIDEPSIN-REACH may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol may make some side effects such as dizziness worse.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• gastro-intestinal problems such as nausea, vomiting, diarrhoea, constipation, stomach pain, indigestion, a loss of appetite, weight loss, or changes in taste.• easy bleeding or bruising in the absence of injury. You may have a low number of platelets, which are the blood cells that help to clot your blood.• weakness, tiredness, dizziness, shortness of breath or pale colour. You may have a low number of red blood cells that carry oxygen.• swelling of hands, ankles or feet; muscle pain or spasms.• signs of dehydration such as dry mouth, increasing thirst, weakness or light-headedness.	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Sudden signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips or tongue or other parts of the body; and/or shortness of breath, wheezing or trouble breathing.• Symptoms of infection such as fever, chills, sore throat, cough, shortness of breath with or without chest pain, mouth ulcers, burning with urination, flu-like symptoms or any other sign of infection. You may have a low number of white blood cells that fight infection. Patients receiving ROMIDEPSIN-REACH can develop serious infections that sometimes lead to death.• Abnormal heart-beat, or feeling dizzy or faint. This could be due to a change in your heart-rate and/or low levels of potassium or magnesium in your blood.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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| <ul style="list-style-type: none">• Sudden pain in your chest or difficulty in breathing. This may be due to blood clots in the artery leading to your lungs.• Pain or swelling in your legs, especially in your lower leg or calves. This may be due to blood clots in the veins of your leg.• Heavy bleeding in the absence of injury. You may have a very low number of platelets, which are the blood cells that help to clot your blood.• Racing heart, extreme fatigue, headaches. You may have a very low number of red blood cells that carry oxygen. | |
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Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ROMIDEPSIN-REACH contains

Active ingredient (main ingredient)	romidepsin
Other ingredients (inactive ingredients)	Solvent: contains povidone (in the powder vial) and anhydrous ethanol and propylene glycol (in the solvent vial).
Potential allergens	Nil

Do not take this medicine if you are allergic to any of these ingredients.

What ROMIDEPSIN-REACH looks like

ROMIDEPSIN-REACH is supplied as a dual pack with one vial containing the white to off-white ROMIDEPSIN-REACH powder and the other vial containing a clear solvent (AUST R 382687).

Who distributes ROMIDEPSIN-REACH

ROMIDEPSIN-REACH are supplied in Australia by:

Reach Pharmaceuticals Pty Ltd
Ground Floor, Corporate One,
84 Hotham Street,
Preston VIC 3072

This leaflet was prepared in December 2022.