

THIOTEPA-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 THIOTEPA-REACH?

THIOTEPA-REACH contains the active ingredient thiotepa. THIOTEPA-REACH is used to prepare patients for bone marrow transplantation. It works by destroying bone marrow cells. This enables the transplantation of new bone marrow cells (haematopoietic progenitor cells), which in turn enable the body to produce healthy blood cells. THIOTEPA-REACH can be used in adults and children and adolescents.

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

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

Do not use if you have ever had an allergic reaction to thiotepa 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 THIOTEPA-REACH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with THIOTEPA-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 THIOTEPA-REACH?

- Your healthcare Professional will decide what dose you will receive. This depends on your condition and other factors such as your weight, kidney function and other chemotherapy medicines you are being given.

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

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

Things you should do	<ul style="list-style-type: none">Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.Undertake regular blood tests during treatment to check your blood cell counts.Treatment with THIOTEPA-REACH reduces the ability of men and women to have children. You should consider discussing ways to preserve your fertility with your doctor before you start treatment.THIOTEPA-REACH is excreted from your skin and can cause irritation. You should wash four times each day while receiving treatment and for 2 days after completion of treatment.
Things you should not do	<ul style="list-style-type: none">You must not get pregnant during treatment with this medicine.Female patients should not breast-feed during treatment.Both men and women should use an effective method of contraception during treatment with THIOTEPA-REACH.Male patients should not father a child during and up to 1 year after treatment.
Drinking alcohol	Tell your doctor if you drink alcohol. Drinking alcohol may make some side effects such as dizziness worse.
Looking after your medicine	This medication is cytotoxic and appropriate precautions must be taken when handling thiotepa. For this reason, your medicine will be handled and stored by trained personnel at the hospital

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

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some of the common side effects

are: decrease in circulating blood cell counts; infection; liver disorders including blocking of a liver vein; bleeding; the transplanted stem cells attack your body cells (graft versus host disease); kidney problems; lung and airway complications; headache; seizures; sore, red mouth; mouth ulcers; nausea; diarrhoea; vomiting; fatigue; pain at injection site; skin rash; hair loss.

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.

THIOTEPA-REACH

Active ingredient(s): *thiotepa*

Consumer Medicine Information (CMI)

This leaflet provides important information about using THIOTEPA-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 THIOTEPA-REACH.**

Where to find information in this leaflet:

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

1. Why am I using THIOTEPA-REACH?

THIOTEPA-REACH contains the active ingredient **THIOTEPA**. THIOTEPA-REACH contains the active substance thiotepa, which belongs to a group of medicines called alkylating agents.

THIOTEPA-REACH is used to prepare patients for bone marrow transplantation. It works by destroying bone marrow cells. This enables the transplantation of new bone marrow cells (haematopoietic progenitor cells), which in turn enable the body to produce healthy blood cells.

THIOTEPA-REACH can be used in adults and children and adolescents.

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

Warnings

Do not use THIOTEPA-REACH if:

- you are allergic to thiotepa, or any of the ingredients listed at the end of this leaflet.
- if you are pregnant or think you may be pregnant,
- if you are breast-feeding.

Check with your doctor if you:

- have liver or kidney problems,
- have heart or lung problems,
- have seizures/fits (epilepsy) or have had them in the past (if treated with phenytoin or fosphenytoin).
- Are hypersensitive to thiotepa or to any of other ingredients in THIOTEPA-REACH
- take any medicines for any other condition
- THIOTEPA-REACH may increase the risk of having another cancer in the future. You will have regular follow up with your doctor after treatment with THIOTEPA-REACH is completed.
- Because THIOTEPA-REACH destroys bone marrow cells responsible for producing blood cells, regular blood tests will be taken during treatment to check your blood cell counts.
- In order to prevent and manage infections, you will be given medicines to treat infection.
- THIOTEPA-REACH impairs male and female fertility. Patients or their carers should discuss fertility preservation **before** therapy is started.
- Men should not father a child while treated and during the year after cessation of treatment.
- Both women and men using THIOTEPA-REACH must use effective contraceptive methods during treatment.

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.

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

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.

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

4. How do I use THIOTEPA-REACH?

How much to take / use

- Your Healthcare Professional will decide what dose you will receive. This depends on your condition and other factors such as your weight, kidney function and other chemotherapy medicines you are being given.
- THIOTEPA-REACH will be given in combination with other drugs or with radiation treatment.
- Several courses of therapy may be needed depending on your response to treatment.
- Additional treatment may not be repeated until your blood cell numbers have returned to acceptable levels and any unwanted effects have been controlled.
- Ask your Healthcare Professional if you want to know more about the dose of THIOTEPA-REACH you receive.

When to take / use THIOTEPA-REACH

THIOTEPA-REACH should be administered by a Healthcare Professional. You may receive medication to reduce nausea before you are given THIOTEPA-REACH.

How to use THIOTEPA-REACH

THIOTEPA-REACH is administered by a qualified Healthcare Professional as an intravenous infusion (drip in a vein) after dilution of the individual vial. Each infusion will last 2-4 hours.

If you use too much THIOTEPA-REACH

THIOTEPA-REACH is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side-effects after being given THIOTEPA-REACH, you may need urgent medical attention.

You should immediately:

- contact your doctor, or contact the National Poisons Centre on 0800 POISON (0800 764 766), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

Things you should do

Keep all follow up appointments with your doctor.

It is important to have your follow-up injections of THIOTEPA-REACH at the appropriate times to get the best effects from your treatment. Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Tell any other doctors, dentists and pharmacists who are treating you that you are having THIOTEPA-REACH.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are having THIOTEPA-REACH.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are having THIOTEPA-REACH.

If you become pregnant while having THIOTEPA-REACH, tell your doctor.

THIOTEPA-REACH can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.
- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
- Avoid contact sports or other situations you may bruise or get injured.

Your body breaks down THIOTEPA-REACH. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomit and semen.

It is important to wash four times daily when receiving THIOTEPA-REACH and for 2 days after completion of treatment so that skin irritation caused by thiotepea is reduced. Only one wash should be with soap and the other washes with water only.

In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste
- Wearing gloves to clean any spill of blood fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet.
- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Using a strong solution of non-bleaching detergent and large amounts of water.
- Place soiled disposable nappies and other pads in a

- plastic, seal and dispose into the garage.
- For sexual intercourse, use a barrier method such as a condom.

Call your doctor straight away if you:

Notice any sign of bleeding or infection. Signs of bleeding may include bruising easily, change in the colour of your urine, black stools or bleeding nose.

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

Things you should not do

- Do not use THIOTEPA to treat any complaint other than that directed by your doctor. It may not be safe to use THIOTEPA-REACH for another complaint.
- Do not have any immunisations while you are having THIOTEPA-REACH or for some time after you have stopped treatment.
Ask your doctor when you can have immunisations.
- Do not drink alcohol while taking THIOTEPA-REACH
Drinking alcohol may make some side effects such as dizziness worse.
- Do not take more than your doctor has prescribed.
High doses of THIOTEPA-REACH may be associated with a serious blood disorder.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how THIOTEPA-REACH affects you.

As with other cytotoxic medicines, THIOTEPA-REACH may cause dizziness, tiredness, headache and blurred vision in some people. Make sure you know how to react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

Keep out of the sight and reach of children.

Store and transport refrigerated (2°C-8°C). Do not freeze.

After reconstitution the product is stable for 8 hours when stored at 2°C -8°C.

After dilution the product is stable for 24 hours when stored at 2°C -8°C and for 4 hours when stored at 25°C. From a microbiological point of view, the product should be used immediately.

When to discard your medicine (as relevant)

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

The most serious side effects of THIOTEPA-REACH therapy or the transplant procedure

- may include decrease in circulating blood cell counts (intended effect of the medicine to prepare you for your transplant infusion)
- infection
- bleeding including into the brain, gut and lungs
- severe skin rash which may be life-threatening
- heart disorders including inflammation and blockage of blood vessels in the heart
- damage to kidneys
- liver disorders including blocking of a liver vein
- the graft attacks your body (graft versus host disease)
- respiratory complications
- male and female infertility
- delirium, seizures
- reduced appetite
- delay in height and body weight increase in children and adolescents

Your doctor will monitor your blood counts and liver enzymes regularly to detect and manage some of these events.

Tell your doctor 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 or in New Zealand to <https://pophealth.my.site.com/carmreportnz/s/>. 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 THIOTEPA-REACH contains

Active ingredient (main ingredient)	thiotepa
Other ingredients (inactive ingredients)	Nil
Potential allergens	Nil

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

What THIOTEPA-REACH looks like

THIOTEPA-REACH is a freeze-dried powder. The powder is first mixed with sterile water and then may be further diluted with sterile water, saline or glucose before it is given to you. The mixed solution is clear to slightly cloudy.

THIOTEPA-REACH 15 mg AUST R 364527

THIOTEPA-REACH 100 mg AUST R 364570

Who distributes THIOTEPA-REACH

THIOTEPA-REACH are supplied in Australia by:

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

New Zealand Sponsor:

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