

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 TEPADINA?

TEPADINA contains the active ingredient thiotepa. TEPADINA 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.

TEPADINA can be used in adults and children and adolescents.

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

2. What should I know before I use TEPADINA?

Do not use if you have ever had an allergic reaction to thiotepa.

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 TEPADINA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TEPADINA 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 TEPADINA?

- Your doctor will calculate the dose according to your body surface or weight and your disease.
- This medicine will be given to you by your doctor. It is given by drip (infusion) into a vein over 2 to 4 hours.

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

5. What should I know while using TEPADINA?

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.• Wash four times a day while using TEPADINA and continue until 48 hours after the last dose.
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.• Male patients should not father a child during and up to 1 year after treatment.
Driving or using machines	<ul style="list-style-type: none">• This medicine can cause dizziness, headache and blurred vision which may reduce your ability to drive or use machines. If you are affected, do not drive or use machines.
Drinking alcohol	<ul style="list-style-type: none">• Talk to your doctor about the risks associated with drinking alcohol before and after your treatment.
Looking after your medicine	<ul style="list-style-type: none">• 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 TEPADINA?](#) in the full CMI.

6. Are there any side effects?

Serious side effects 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. 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.

TEPADINA®

Active ingredient: *thiotepa*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TEPADINA. **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 TEPADINA.**

Where to find information in this leaflet:

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

1. Why am I using TEPADINA?

TEPADINA contains the active ingredient THIOTEPA. TEPADINA belongs to a group of medicines called alkylating agents.

TEPADINA 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.

TEPADINA can be used in adults and children and adolescents.

2. What should I know before I use TEPADINA?

Warnings

Do not use TEPADINA if:

- you are allergic to thiotepa,
- 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,
- heart or lung problems
- seizures/fits (epilepsy) or have had them in the past.

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?](#)

TEPADINA may increase the risk of having another cancer in the future. You will have regular follow up with your doctor after treatment with TEPADINA is completed.

Because TEPADINA 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.

Pregnancy and breastfeeding

You must tell your doctor if you are pregnant or you think you may be pregnant before you receive TEPADINA. You must not use TEPADINA during pregnancy.

Both women and men using TEPADINA must use effective contraceptive methods during treatment.

Men should not father a child while treated with TEPADINA and during the year after cessation of treatment.

It is not known whether this medicinal product is excreted in breast milk. As a precautionary measure, women must not breast-feed during treatment with TEPADINA.

TEPADINA can impair male and female fertility. Women should discuss fertility preservation with their physician before treatment. Male patients should seek advice for sperm preservation before therapy is started.

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.

TEPADINA may interfere with some medicines and affect how they work. These medicines include:

- some medicines for prevention of blood clots (clopidogrel, ticlopidine)
- some medicines to treat fungal infections (fluconazole, itraconazole, voriconazole, posaconazole, isavuconazole, ketoconazole, amphotericin B)
- some medicines to treat bacterial infections (erythromycin, clarithromycin, telithromycin)
- some antiviral medicines to treat HIV (efavirenz, protease inhibitors)
- some medicines used to treat epilepsy and seizures (including rifampicin, carbamazepine, phenobarbital)
- some medicines for the treatment of cancer (ifosfamide, tamoxifen, and cyclophosphamide)
- bupropion, a medicine used for smoking cessation and weight loss
- ondansetron, a medicine used for treatment and prevention of nausea and vomiting

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

4. How do I use TEPADINA?

How much to use

This medicine is used in combination with other chemotherapeutic agents. Your doctor will calculate the dose according to your body surface area or weight and your disease.

How TEPADINA is given

TEPADINA is administered by a qualified healthcare professional as an intravenous infusion (drip in a vein) after dilution of individual vial or reconstitution of the individual bag. Each infusion will last 2-4 hours.

You will receive your infusions every 12 or 24 hours. The duration of treatment can last up to 5 days. Frequency of administration and duration of treatment depend on your disease.

If you forget to use TEPADINA

As you will be given this medicine by a doctor or a nurse it is unlikely that a dose will be missed.

If you use too much TEPADINA

This medicine is given by a doctor or nurse. However, if you think you have received more of this medicine than you should, tell your doctor or nurse as soon as possible.

5. What should I know while using TEPADINA?

Things you should do

Because TEPADINA 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 anti-infectives.

Wash four times a day while using TEPADINA, with one wash using soap and the remaining three washes with water only. Showering is preferred. Four times a day washing should continue until 48 hours after the last dose.

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

Remind any doctor, dentist, pharmacist or nurse you visit that you are using TEPADINA.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TEPADINA affects you.

It is likely that certain adverse events of thiotepa like dizziness, headache and blurred vision could affect your ability to drive and use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Your doctor will explain the risks associated with drinking alcohol before and after your treatment.

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.

TEPADINA is stored at 2°C to 8°C (Refrigerate. Do not freeze).

Keep it where young children cannot reach it.

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 the transplant conditioning and procedure may include the following:

- 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 carry out blood tests 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 online at <https://nzphvc.otago.ac.nz/reporting/>. 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.

- vial containing 100 mg thiotepa powder for injection
- bag containing 400 mg thiotepa powder for injection and solvent for infusion

Who distributes TEPADINA

In Australia:
Link Medical Products Pty Ltd
5 Apollo Street
Warriewood NSW 2102

In New Zealand:
Link Pharmaceuticals Ltd
Suite 38, Level 8
139 Quay Street
Auckland 1010
Telephone: +64 (9) 358 7146

Under license from ADIENNE SA, Via Zurigo 46, 6900 Lugano, Switzerland

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7. Product details

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

What TEPADINA contains

TEPADINA 15 and 100 mg	
Active ingredient (main ingredient)	thiotepa
Other ingredients in powder (inactive ingredients)	None
TEPADINA 400 mg	
Active ingredient (main ingredient)	thiotepa
Other ingredients in powder (inactive ingredients)	None
Other ingredients in solvent (inactive ingredients)	Sodium chloride Water for injections

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

What TEPADINA looks like

TEPADINA is a white crystalline powder in a glass vial with a rubber stopper and aluminium cap (15 mg and 100 mg) or a dual chamber bag containing 400 mg thiotepa and 400 mL sodium chloride 9 mg/mL (0.9%) solution for infusion.

TEPADINA is available in:

- vial containing 15 mg thiotepa powder for injection