

THIOTEPA

thiotepa injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about THIOTEPA. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking THIOTEPA against the benefits they expect it will have for you.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

What THIOTEPA is used for

THIOTEPA is used to treat some types of cancer. These include cancer of the breast, ovary and bladder.

It is also used to control fluid leaking into body spaces, which have been affected by secondary tumours.

THIOTEPA belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy or anticancer medicines.

This medicine is given as an injection into a vein or directly into an organ or body space.

THIOTEPA works by interfering with the growth of cancer cells. This slows their growth and eventually destroys them. The growth of normal cells in other parts of the body is affected as well.

This medicine is not addictive.

It is available only with a doctor's prescription.

THIOTEPA is not recommended for use in children, as there is not enough information on its effects in children.

Before you are given it

When you must not be given it

Do not have this medicine if:

- 1. You have an allergy to THIOTEPA**
Symptoms of an allergic reaction to THIOTEPA may include:
 - shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching, hives or flushed, red skin
 - dizziness or light-headedness
 - back painYour doctor may give you a small test dose to see how you react to THIOTEPA.
- 2. You are pregnant or intend to become pregnant**
Like most medicines used to treat cancer, THIOTEPA is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.
It may affect your developing baby if you take it during pregnancy. It is recommended that you use some kind of effective birth control while taking THIOTEPA and for at least 12 weeks after you stop using it. Your doctor will discuss this with you.

3. You are breast-feeding or plan to breast-feed

It is recommended that you do not breast-feed while taking THIOTEPA, as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

4. You have, or have had, any of the following medical conditions:

- severe liver disease
- kidney disease
- bone marrow damage

In some cases your doctor may still choose to give you THIOTEPA if you have any of these conditions. If your doctor gives you THIOTEPA, you will have tests carried out on your liver, kidney and blood during treatment.

Do not have it if the packaging is torn or shows signs of tampering.

Do not have it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

If it has expired or is damaged, return it to your pharmacist for disposal.

Talk to your doctor or pharmacist if you are not sure whether you should start having THIOTEPA.

Before you are given it

You must tell your doctor if:

- 1. you have any allergies to:**
 - any other medicines
 - any other substances, such as foods, preservatives or dyes
- 2. you plan to father a child**
Tell your doctor or pharmacist if your partner intends to become pregnant while you are using THIOTEPA or shortly after you have stopped using THIOTEPA.
It is recommended that you use some kind of effective birth control while taking THIOTEPA and for at least 12 weeks after you stop using it. Your doctor will discuss this with you.

If you have not told your doctor about any of the above, tell them before you take any THIOTEPA.

Taking other medicines

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

Some medicines may interfere with THIOTEPA. These include:

- other medicines used to treat cancer, radiation therapy or any other treatment which lowers your immune system

These medicines may increase the effects of THIOTEPA. You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist may have more information on medicines to be careful with or avoid while taking THIOTEPA.

How it is given

How much is given

Your doctor 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 may be given alone or in combination with other drugs.

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 doctor if you want to know more about the dose of THIOTEPA you receive.

How it is given

THIOTEPA is usually given as an injection into your veins (intravenously) or into a body space. This medicine must only be given by a doctor or nurse.

In people with cancer of the bladder, you will not be allowed to drink fluids for 8 to 12 hours before treatment. Then 60mg THIOTEPA along with 30-60mL of water is given through a rubber tube (called a catheter) into your bladder. This solution is then kept in your bladder for 2 hours.

How long it is given

For most cancers, THIOTEPA is usually given at one to four week intervals.

For cancer of the bladder, the usual course of treatment is once a week for 4 weeks. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

Overdose

As THIOTEPA 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 tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention

Symptoms of a THIOTEPA overdose include the side effects listed below in the 'Side effects' section, but are usually of a more severe nature.

While you are using it

Things you must do

Keep all follow up appointments with your doctor.

It is important to have your follow up injections of THIOTEPA 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.

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

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

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

Tell your doctor 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.

THIOTEPA 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 where you may bruise or get injured.

Your body breaks down THIOTEPA and uses it to fight cancer. 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 body 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. Use 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 garbage.
- For sexual intercourse, use a barrier method such as a condom.

Things you must not do

Do not give THIOTEPA to anyone else, even if they have the same condition as you.

Do not use THIOTEPA to treat any other complaints unless your doctor or pharmacist tells you to.

Do not have any immunisations while you are having THIOTEPA or for some time after you after stopped treatment.

Ask your doctor when you can have immunisations.

Do not drink alcohol while taking THIOTEPA.

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

Do not to take more than your doctor has prescribed.

High doses of THIOTEPA may be associated with a serious blood disorder.

Things to be careful of

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

As with other cytotoxic medicines, THIOTEPA may cause dizziness, tiredness, headache and blurred vision in some people. Make sure you know how you 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.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are having this medicine.

Like other medicines that treat cancer, it may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- Fever
- Tiredness
- Difficulty breathing or swelling of the throat
- Pain at injection site
- Feeling sick or nausea
- Vomiting
- Stomach pain
- Loss of appetite
- Difficulty passing urine
- Pain when passing urine
- Dizziness
- Headache
- Blurred vision
- Loss of menstrual periods
- Lowering of sperm count
- Skin rash or dermatitis
- Hair loss

These are the more common side effects of THIOTEPA.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- Tiredness, headaches, dizziness, being short of breath when exercising and looking pale
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers
- Bleeding or bruising more easily than normal, nosebleeds.

These may be serious side effects and may be a sign that your bone marrow is depressed and you may need medical attention.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

The benefits and side effects of THIOTEPA may take some time to occur. Therefore even after you have finished your THIOTEPA treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

After using it

Storage

THIOTEPA will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Product description

What it looks like

THIOTEPA 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.

Ingredients

THIOTEPA contains the active ingredient thiotepa. Each vial contains 15mg thiotepa.

There are no inactive ingredients.

THIOTEPA does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Manufacturer

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

Australian Registration Number:
THIOTEPA 15mg Powder for Injection
AUST R 43083

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