TOMUDEX™

Raltitrexed (ral-ti-TREX-ed)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Tomudex™. It does not contain all the information that is known about this medicine.

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

All medicines have risks and benefits. Your doctor will have weighed the risks of you receiving Tomudex™ against the benefits they expect it will have for you.

If you have any concerns about receiving this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What Tomudex™ is used for

Tomudex™ belongs to a group of medicines called cytotoxic agents. These agents are used for the treatment of cancer. They kill cells within your body, which cause certain types of malignant growths or cancer. Cells which are dividing (or growing) have to make certain chemicals. This medicine blocks the formation of these chemicals.

Tomudex™ is used to treat cancer which affects the colon and rectum (parts of your large intestine or bowel). Your doctor will help you understand the benefits of having this medicine for your particular problem.

Your doctor will have explained why you are being treated with Tomudex™ and told you what dose you will be given.

Follow all directions given to you by your doctor.
They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Tomudex™ is not addictive.

Before you use Tomudex™

When you must not use it

Do not use Tomudex™ if you are pregnant or breastfeeding.
We do not know if it is safe for you to be given it while you are pregnant. It may affect your baby if you are given it at any time during pregnancy.

Your baby may take in Tomudex™ from breast milk if you are breastfeeding.

Do not give Tomudex™ to children.
There is no information on its use in children.

Tomudex™ should not be given to patients with severe kidney disease.

Do not use after the use by (expiry) date printed on the pack.
It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use Tomudex™ if the packaging is torn or shows signs of tampering.

Tomudex™ infusions should not be given to anyone other than the patients for whom they are prescribed.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

Before you start to use it

Tell your doctor if:

1. **you have any allergies to:**
- Raltitrexed, the active ingredient in Tomudex™
- any ingredients of Tomudex™ listed at the end of this leaflet.
  If you have an allergic reaction, you may get a skin rash, hay fever, difficulty breathing or feel faint.

2. **you have any of these medical conditions**
- liver problems
- kidney problems
- blood or bone marrow problems
- stomach or bowel (intestinal) problems.
  It may not be safe for you to be given Tomudex™ if you have any of these conditions.

3. **you have previously had radiotherapy (treatment with high dose X-rays).**
4. **you and your partner are hoping to start a family.**
   It is recommended that pregnancy should be avoided during treatment and for at least 6 months after completion of treatment if either partner is receiving Tomudex™.
5. **you have been given Tomudex™ before and experienced any of the following:**
- soreness or ulceration of the inside of your mouth

- diarrhoea.

Receiving other medicines

Tell your doctor if you are receiving any other medicines, including:

- any medicine which contains folinic or folic acid
- vitamins or vitamin supplements
- anticoagulant (a medicine to prevent blood clotting)
- medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way Tomudex™ works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. If you have not told your doctor about any of these things, tell them before you are given any TOMUDEX™.

Using Tomudex™

Receiving Tomudex™

Your Tomudex™ injection will be given to you under the supervision of a doctor who is a specialist in the use of this type of medicine.

This supervision means that side effects will be found and treated quickly.

You should follow any instructions that your doctor gives you about your treatment. If you are not sure about anything you should ask your doctor.

Tomudex™ is administered by intravenous infusion (directly into your blood) usually over a short period of time (about 15 minutes).

The exact dose of Tomudex™ you are given will be decided by your doctor. It will vary depending on your physical size and how you react to the treatment. The results of your blood tests will also help the doctor to decide what dose you will receive. The usual dose is 3 mg/m^2, body surface area (i.e. you will receive 3mg for each square metre of body surface area, calculated from your height and weight). The dose you are given may vary depending on your response to treatment.

Tomudex™ is usually given every 3 weeks. This may be prolonged depending on the results of regular blood tests.

If your dose is missed or delayed

You should be given Tomudex™ as prescribed by your doctor. Your doctor may decide to prolong the time in between treatments. If you have any concerns or questions about the time between Tomudex™ doses, please ask your doctor.

If you take too much (overdose)

Tomudex™ will be given to you under the supervision of a doctor who is a specialist in the use of this type of medicine. Contact your doctor or nursing staff immediately if you think you have been given more than your prescribed dose of Tomudex™ even if there are no signs of discomfort or poisoning.

Your doctor will know what measures to take in this situation.

Do this even if there are no signs of discomfort or poisoning.

While you are receiving Tomudex™

Things you must do

Be sure to keep all your appointments with your doctor so your progress can be checked.

Tell any other doctors, dentists and pharmacists who are treating you that you are receiving Tomudex™.

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

If you go into hospital, please let the medical staff know that you are receiving Tomudex™. Your doctor will tell you for how long you will need to receive Tomudex™.

While you are receiving the medicine, your doctor will need to take regular samples of your blood. He/she will use the results from these to decide your dose of Tomudex™.

If you are unsure about any of these points or have further questions please tell your doctor or pharmacist.

Things you must not do

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

Do not use Tomudex™ to treat any other complaints unless your doctor tells you to.

Things to be careful of

Your medicine is unlikely to adversely affect your ability to drive a car or to operate machinery. However, some patients may experience a flu-like syndrome, or a general feeling of being unwell, for a short time after receiving Tomudex™. If you do experience these effects you should not drive or operate machinery.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are receiving Tomudex™.
Tomudex™ helps most people with cancer of the colon and rectum, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Sometimes side effects may be symptoms of the cancer you are being treated for. 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 if you notice any of the following and they worry you:

- nausea, vomiting or diarrhoea
- loss of appetite, weight loss or constipation
- swelling of the abdomen, abdominal pain or indigestion
- hiccups or flatulence
- sore throat, sore or dry mouth, mouth ulcers, oral thrush or cold sores
- dehydration (feeling thirsty and/or dry skin)
- swollen hands, ankles or feet
- painful or swollen joints, muscle cramps, aching or tenderness headache or dizziness
- fever, chills, infection, flu-like symptoms or conjunctivitis (red and/or itchy eyes)
- generally feeling unwell, tired or weak
- back pain, chest pain or general pain, shortness of breath or difficulty breathing
- tingling or numbness of the hands or feet
- skin rash, tenderness or swelling under the skin, itching, peeling of the skin or hair loss (thinning)
- sweating or altered taste
- any unusual bleeding or bruising

In addition Tomudex™ may cause abnormalities of your blood, due to effects on your bone marrow or your liver. Your doctor will check your blood regularly to detect whether abnormalities have occurred.

Diarrhoea may be particularly severe and could require urgent medical attention.

Do not be alarmed by this list of possible events. You may not experience any of them.

Tell your doctor if you notice anything else that is making you feel unwell.
Some people may get other side effects while receiving Tomudex™.

After receiving Tomudex™

Storage

Tomudex™ will either be stored for you by the hospital or dispensed to you prior to administration. It will be kept in a cool dry place where the temperature stays below 25°C.

The hospital staff are responsible for the use and disposal of Tomudex™.

Keep it where young children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Tomudex™ will normally be disposed of by the hospital. After the medicine is administered to you the hospital staff are responsible for the disposal of Tomudex™.

Product description

What Tomudex™ looks like

Tomudex™ comes as a powder, which is then made into a solution for infusion.

The powder is contained in a clear glass vial and packed in individual cartons. This powder will be mixed by the pharmacist, nurse or doctor with sterile water and then added to a sterile salt solution or glucose solution to give a clear solution ready for injection. This mixing will be done in a special area designed for this type of procedure.

Ingredients

Active ingredients:
Each vial of Tomudex™ contains:

- 2 mg of Raltitrexed.

Inactive ingredients:

- mannitol
- dibasic sodium phosphate
- sodium hydroxide.

Tomudex™ does not contain gluten, sucrose, tartrazine or any other azo dyes.

How can Tomudex™ be obtained

You must have a prescription from a doctor. The injection will usually be supplied for you by the hospital pharmacy. Your doctor, pharmacist and nurse will tell you about Tomudex™.

Distributor

Tomudex™ is distributed in Australia by:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

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2mg per vial AUST R 54638