

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tomudex® 2mg Injection raltitrexed

Read all of this leaflet carefully before you start having this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

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1. What Tomudex is and what it is used for

Tomudex contains a medicine called raltitrexed. This belongs to a group of medicines known as chemotherapy. These are used to treat cancer.

Tomudex is used to treat cancer which affects the colon and rectum (parts of your 'bowel' or gut).

It works by killing cells within your body which cause certain types of cancer. Your doctor will probably explain this to you in more detail.

2. Before you are given Tomudex

Do not have Tomudex if:

- You have severe kidney disease.
- You are pregnant, think you might be pregnant, are trying for a baby or you are breast-feeding (see the section on 'Pregnancy and breast-feeding').
- You are taking leucovorin or folic acid or any vitamins containing these.

Do not have Tomudex if any of the above apply to you. If you are not sure, talk to your doctor or nurse before having Tomudex.

Tomudex should not be given to children.

Take special care with Tomudex

Check with your doctor or nurse before having Tomudex if you have ever had:

- Any problems with your blood, kidneys or liver.
- Radiotherapy (treatment with high dose X-rays).

Please tell your doctor or nurse if there is a change in your stomach or bowel (gut) problems whilst taking Tomudex.

If you are elderly, your doctor or nurse will monitor you more closely for side effects. Elderly people can be more affected by the side effects of this kind of medicine.

If you have any other treatment for other problems or illnesses, tell your doctor, nurse or pharmacist that you are having Tomudex.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before having Tomudex.

Taking other medicines

Please tell your doctor, nurse or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Tomudex can affect the way some medicines work and some medicines can have an effect on Tomudex.

In particular, tell your doctor, nurse or pharmacist if you are taking any of the following:

- Vitamins or vitamin supplements.
- Medicines to thin your blood and stop it clotting (anti-coagulants).

Pregnancy and breast-feeding

- Do not have Tomudex if you are pregnant, think you may be pregnant or might become pregnant. This is because it may affect your baby.
- You should not try for a baby when either partner is having Tomudex, during the treatment or for at least 6 months after stopping treatment. This is because it may affect the baby.
- Do not have Tomudex if you are breast-feeding.

Driving and using machines

You may feel generally unwell or have flu-like symptoms for a short time after having Tomudex. If this happens, do not drive or use any tools or machines.

3. How Tomudex will be given

- **You will be given Tomudex by a doctor or nurse who is a specialist in the use of this type of medicine.**
- Tomudex will be injected slowly into one of your veins. The injection will usually take 15 minutes.
- The exact dose you are given will be decided by your doctor. It will depend on your size and how you react to your treatment.
- The usual dose is 3 milligrams for each square metre of your body surface area. Your doctor will calculate this from your height and weight.
- Your doctor will need to take regular samples of your blood while you are having Tomudex. The results of your blood tests will also help the doctor to decide what dose you will receive. The dose you are given may be different each time.
- Tomudex is usually given every 3 weeks, but it could be less often, depending on the results of your blood tests.

You should follow any instructions that your doctor gives you about your treatment.

If you are not sure about anything ask your doctor or nurse.

4. Possible side effects

Like all medicines, Tomudex can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Tell your doctor or the hospital straight away if you notice any of the following side effects – you may need urgent medical treatment:

Very common (affects more than 1 user in 10)

- **Diarrhoea.**
- **Being sick (vomiting).**
- **High temperature (fever) or chills.**
- **Mucositis (inflammation of the mouth and gut lining).**

Common (affects 1 to 10 users in 100)

- **Sore throat.**
- **Any infections.**
- **Soreness or ulcers inside your mouth.**

Not known (frequency cannot be estimated from available data)

- **Bleeding from the gut.**

Other possible side effects are:

Very common (affects more than 1 user in 10):

- Loss of appetite.
- Indigestion.
- Feeling sick (nausea).
- Stomach pain.
- Constipation.
- Weight loss.
- Itchy rash.
- Tomudex may cause changes to your blood. These occur because of effects on your bone marrow and your liver. Your doctor will take regular blood samples to check your blood.

Common (affects 1 to 10 users in 100):

- Painful joints.
- Muscle cramps.
- Swollen hands, ankles or feet.
- Yellow skin and eyes (jaundice).
- Tenderness and swelling under the skin (cellulitis).
- Sweating.
- Hair loss or thinning.
- Feeling thirsty or dry skin (signs of dehydration).
- Headache.
- Altered taste.
- Red or itchy eyes (conjunctivitis).
- Weakness (sometimes flu-like symptoms).

Uncommon (affects 1 to 10 users in 1000):

- Red or peeling skin.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5. How to store Tomudex

This medicine will normally be stored for you by the hospital. The doctor and hospital pharmacist are responsible for storing, using and disposing of Tomudex correctly.

- Keep out of the reach and sight of children.
- Keep unopened vials in the outer carton to protect them from light.
- Do not store above 25°C.
- Do not use Tomudex after the expiry date which is stated on the vial. The expiry date refers to the last day of that month.

6. Further information

What Tomudex contains

The active substance is raltitrexed. Each vial contains 2mg of raltitrexed.

The other ingredients are mannitol, dibasic sodium phosphate heptahydrate or dodecahydrate and sodium hydroxide.

What Tomudex looks like and the contents of the pack

Tomudex comes in containers of single glass vials containing a powder which is then made into a solution for injection into a vein. The vials are packed in cartons.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Tomudex is held by Hospira UK Limited, Queensway, Royal Leamington Spa, Warwickshire, CV31 3RW, United Kingdom.

Tomudex is manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK or Hospira UK Limited, Queensway, Royal Leamington Spa, Warwickshire, CV31 3RW, UK.

Leaflet updated: October 2011

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