

Package leaflet: Information for the user

Tomudex® 2mg powder for solution for infusion raltitrexed

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tomudex is and what it is used for
2. What you need to know before you use Tomudex
3. How to use Tomudex
4. Possible side effects
5. How to store Tomudex
6. Contents of the pack and other information

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.

What is it used for?

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. What you need to know before you use Tomudex

Do not use Tomudex:

- if you are allergic to raltitrexed or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney disease.
- if 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').
- if you are taking leucovorin or folic acid or any vitamins containing these.

Tell your doctor if any of the above applies to you before this medicine is used.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Tomudex:

- if you have any problems with your blood, kidneys or liver.

- if you have had 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.

Children

This medicine should not be used in children.

Other medicines and Tomudex

Talk to your doctor, pharmacist or nurse if you are using, have recently used, or might use 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, pharmacist or nurse if you are using any of the following:

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

Tomudex with food and drink

There are no special recommendations concerning the use of this medicine with food and drink.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, you should not use Tomudex. Ask your doctor or pharmacist for advice before using Tomudex.

You should not try for a baby when either partner is using Tomudex, during the treatment or for at least six months after stopping treatment. This is because it may affect your baby.

Breast-feeding

Do not use this medicine 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.

Information about the ingredients of Tomudex

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How to use Tomudex

Dosage and method of administration

You will be given this medicine 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 three weeks, but it could be less often, depending on the results of your blood tests.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine 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: may affect more than 1 in 10 people

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

Common: may affect up to 1 in 10 people

- **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: may affect more than 1 in 10 people:

- 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: may affect up to 1 in 10 people:

- 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: may affect up to 1 in 100 people:

- Red or peeling skin.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tomudex

Keep this medicine out of the sight and reach of children.

Expiry date

Do not use Tomudex after the expiry date which is stated on the vial label and carton. The expiry date refers to the last day of that month.

Storage

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.

Do not store above 25°C. Keep unopened vials in the outer carton to protect them from light.

6. Contents of the pack and other 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 white to cream coloured powder.

Marketing Authorisation Holder

Hospira UK Limited
Walton Oaks
Walton-On-The-Hill
Dorking Road
Tadworth
Surrey
KT20 7NS
UK

Manufacturer

Pfizer Service Company BV
Hoge Wei 10

1930 Zaventem
Belgium

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