

# **PACKAGE LEAFLET: INFORMATION FOR THE USER**

## **Tomudex® 2 mg Powder for Solution for Infusion**

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:**

1. What Tomudex is and what it is used for
2. Before you are given Tomudex
3. How Tomudex will be given
4. Possible side effects
5. How to store Tomudex
6. Further information

## **1. What Tomudex is and what it is used for**

Tomudex contains a medicine called raltitrexed which is used to treat cancer. Treatment with an anti-cancer medicine is sometimes called cancer chemotherapy.

Tomudex is used to treat:

- cancer which affects the colon and rectum (parts of your 'bowel' or gut).
- malignant pleural mesothelioma (a type of lung cancer) and is given together with other anti-cancer medicine (cisplatin) to patients who have not had chemotherapy previously.

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 folinic acid (leucovorin) or folic acid or vitamins containing either of these.
- You are allergic (hypersensitive) to raltitrexed or any of the other ingredients of Tomudex (see Section 6 Further Information – What Tomudex contains).

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, bone marrow, 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.

Check with your doctor or nurse before having Tomudex if you have a poor general state of health.

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.

Tomudex is not recommended if you have severe liver problems.

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:

- Folinic or folic acid
- Vitamins or vitamin supplements
- Medicines to thin your blood and stop it clotting (anti-coagulants) e.g. warfarin
- Non-steroidal anti-inflammatory drugs (NSAIDs) e.g. aspirin and ibuprofen

### **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. Tell your doctor immediately if you notice any of the following side effects:

##### **Not known (frequency cannot be estimated from available data)**

- Allergic reaction (anaphylactic reaction), symptoms of which include swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), a sudden itchy rash (hives) and you may feel you are going to faint.
- Bleeding from the gut.

##### **Very common (affects more than 1 user in 10)**

- Diarrhoea
- Vomiting (being sick)
- High temperature (fever) or chills
- Mucositis (inflammation of the mouth and gut lining)
- Soreness or ulcers inside your mouth

##### **Common (affects 1 to 10 users in 100)**

- Sore throat
- Infections

Tell you doctor as soon as possible if you notice any of the following side effects:

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

- Loss of appetite
- Indigestion
- Feeling sick (nausea)
- Stomach pain
- Constipation
- Weight loss
- Itchy rash
- Feeling generally unwell
- Tomudex may cause changes to your blood. These occur because of effects on your bone marrow (e.g. low red blood cells (anaemia), low white blood cells and low platelets) and your liver (liver enzyme changes). Your doctor will take regular blood samples to check your blood
- Headache
- Fatigue
- Cough
- Difficulty in breathing
- Chest pain
- Feeling dizzy or light-headed
- Loss of sensation
- Ringing in the ears
- Hair loss or thinning
- Swelling due to too much fluid in body tissues (oedema)

**Common (affects 1 to 10 users in 100):**

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

**Reporting of Suspected Adverse Reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL – Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: <http://www.hpra.ie/>

Email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

**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
- When the powder has been made into a solution (reconstituted), if not used immediately, it should be refrigerated and used within 24 hours

**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 and sodium hydroxide.

**What Tomudex looks like and the contents of the pack**

Tomudex is presented as a powder for solution for infusion. It comes in containers of single glass vials containing a powder which is then made into a solution and given using a drip (infusion) 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, Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, UK.

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