

# TOMUDEX®

raltitrexed

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I being treated with TOMUDEX?

TOMUDEX contains the active ingredient raltitrexed. TOMUDEX is a cytotoxic agent (chemotherapy) used to treat cancer which affects the colon and rectum (parts of your large intestine or bowel). For more information, see Section [1. Why am I being treated with TOMUDEX?](#) in the full CMI.

### 2. What should I know before treatment with TOMUDEX?

You should not be given TOMUDEX if you have ever had an allergic reaction to raltitrexed or any of the ingredients listed at the end of the CMI; are taking calcium folinate (folic acid) or vitamin preparations with

folate; have severe kidney problems; are pregnant or may become pregnant or are breastfeeding.

**Talk to your doctor if you have any other medical conditions, including problems with your liver, kidneys, blood or bone marrow, stomach or bowel problems; or take any other medicines. Pregnancy must be avoided (including your partner if you are male) while being treated with TOMUDEX, and for 6 months after treatment.**

For more information, see Section [2. What should I know before treatment with TOMUDEX?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with TOMUDEX and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How is TOMUDEX given?**

Your doctor will decide how much you will be given and for how long. TOMUDEX is given as a slow drip into a vein. More instructions can be found in Section [4. How is TOMUDEX given?](#) in the full CMI.

## 5. What should I know while I am being treated with TOMUDEX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist and nurse who are treating you that you are being given this medicine.</li><li>• Tell your doctor immediately if you or your partner become pregnant. Effective contraception must be used while receiving this medicine and for at least 6 months after</li></ul>
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	<p>stopping treatment for both females and males.</p> <ul style="list-style-type: none"> <li>• Keep all of your doctor's appointments so your progress can be checked.</li> <li>• Tell your doctor straight away if you experience certain side effects (refer to Section 5 in the full CMI).</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not breastfeed while you are being treated with TOMUDEX.</li> </ul>

<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machines until you know how TOMUDEX affects you.</li> </ul>
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For more information, see Section [5. What should I know while I am being treated with TOMUDEX?](#) in the full CMI.

## 6. Are there any side effects?

Side effects of this medicine may include diarrhoea, loss of appetite, weight loss, constipation; nausea and vomiting, abdominal pain or indigestion, flatulence; blistering of the digestive tract with risk of bleeding; sore throat, dry mouth, mouth ulcers, oral thrush or cold sores; inflammation or bleeding in mouth/throat; unusual bleeding or bruising; yellowing of the skin/eyes, changes in urine colour, fatigue; dehydration; muscle aches and cramps, sadness, insomnia; dizziness; tingling or numbness of the hands/feet; hiccups, runny or itchy nose that may bleed; hair loss, dry rash and itchy/peeling of skin, sweating, altered taste; generally feeling unwell with flu-like symptoms; back/chest pain; fever, chills, infection, low blood pressure, fast heart rate or mental confusion.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



# TOMUDEX®

**Active ingredient(s):** raltitrexed

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## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using TOMUDEX.

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TOMUDEX.**

**Where to find information in this leaflet:**

- [1. Why am I being treated with TOMUDEX?](#)
- [2. What should I know before treatment with TOMUDEX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is TOMUDEX given?](#)
- [5. What should I know while I am being treated with TOMUDEX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I being treated with TOMUDEX?**

**TOMUDEX contains the active ingredient raltitrexed.** TOMUDEX belongs to a group of medicines known as anti-neoplastic or cytotoxic agents, and also referred to as a chemotherapy medicine. These medicines are used

for the treatment of cancer. TOMUDEX works by killing cancer cells and stopping cancer cells from growing and multiplying.

**TOMUDEX is used to treat cancer which affects the colon and rectum (parts of your large intestine or bowel).**

## **2. What should I know before treatment with TOMUDEX?**

### **Warnings**

**You must not be given TOMUDEX if:**

- you are allergic to raltitrexed or to any ingredients listed at the end of this CMI
- you are taking calcium folinate (folic acid) or vitamin preparations with folate as these preparations may interfere with the medication
- you have severe kidney problems
- are pregnant, may become pregnant during treatment, or are breastfeeding

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes. If you are not sure if you are allergic to any of the above, ask your doctor.**

**Check with your doctor if you have any other medical conditions such as:**

- kidney disease



- problems with your liver
- blood and bone marrow disorder with reduced number of red blood cells, white blood cells or platelets.
- stomach or bowel (intestinal) problems such as diarrhoea.

Tell your doctor if you have previously had radiation therapy (treatment with high dose X-rays).

Your doctor may need to cease, delay or reduce treatment depending on your white blood cell count.

**Tell your doctor if you have been given TOMUDEX before and experienced any of the following:**

- soreness or ulceration of the inside of your mouth
- unusual bruising or bleeding
- diarrhoea

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy**

TOMUDEX may have serious effects on a developing baby.

Females: Talk to your doctor if you are pregnant, or plan to become pregnant. TOMUDEX must not be used in women who are pregnant, may become pregnant or are breastfeeding. Pregnancy should be excluded before treatment with TOMUDEX is commenced.

Males: Pregnancy must be avoided while you are being treated with TOMUDEX. Tell your doctor if your partner becomes pregnant or plans to become pregnant while you are being treated with this medicine.

Females and males: It is recommended that pregnancy should be avoided for at least 6 months after completion of treatment. This includes if your partner is receiving TOMUDEX.

**Talk to your doctor about the need for additional contraception while being given TOMUDEX.**

## **Breastfeeding**

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You must not breastfeed during treatment with TOMUDEX, and for a period of time after treatment has finished.

TOMUDEX may pass into breast milk as there may be potential serious side effects to your baby.

Talk to your doctor who will provide you with appropriate instruction.

## **Use in children**

The safety and effectiveness of TOMUDEX in children have not been established.

## Use in the elderly

If you are over 65 years of age there may be a greater chance of kidney issues when using TOMUDEX. Your doctor may order extra tests and will monitor you closely for this.

### **3. What if I am taking other medicines?**

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

**Some medicines may interfere with TOMUDEX and affect how it works.**

**These include:**

- medicines containing calcium folinate, folic acid or vitamin preparations containing folate.
- medicines containing warfarin, used to treat or prevent blood clots
- non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin and ibuprofen, used to treat pain, inflammation or reduce temperature.
- other medicines used to treat cancer containing cisplatin, carboplatin or oxaliplatin.
- other treatments such as radiation therapy or any other treatment which lowers your immune system

Your doctor or pharmacist has more information on medicines to be careful with or avoid while being given TOMUDEX.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TOMUDEX.**

## **4. How is TOMUDEX given?**

### **How much is given**

Your doctor will decide how much TOMUDEX you should receive and the length of time for which you should receive it. This depends on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being given.

### **How is it given**

TOMUDEX is usually given as intravenous infusion (as a slow drip into a vein) over a period of 15 minutes.

### **How long will it be given for**

TOMUDEX is usually given once every 3 weeks. Each infusion is called one 'cycle' of chemotherapy. Your doctor will decide how many of these cycles you will need.

Several courses of TOMUDEX therapy may be needed depending on your response to treatment.

If you have any concerns or questions about the time between TOMUDEX doses, please ask your doctor.

Your doctor will decide if TOMUDEX is given alone or in combination with other drugs.

## **If you are given too much TOMUDEX**

As TOMUDEX is given under supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects, after being given this medicine, tell your doctor or nurse immediately. You may need urgent medical attention.

Symptoms of a TOMUDEX overdose may include the side effects listed in Section 6. 'Side effects' section but are usually of a more severe nature. Alert your doctor immediately if you experience severe diarrhoea; redness, swelling, pain, sores, ulcers or bleeding in the mouth or throat; fever, chills; severe cough or shortness of breath; any abnormal bruising or bleeding including nosebleeds, bleeding gums, heavy periods, or blood in your stool (poo) or urine (wee).

**Tell your doctor or nurse immediately if you are concerned that you may have been given too much TOMUDEX.**

## **5. What should I know while I am being treated with TOMUDEX?**

### **Things you should do**

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with TOMUDEX.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given this medicine.

Tell your doctor or nurse immediately if;

- you are having radiation therapy
- you or your partner become pregnant while taking this medicine
- you are going to have surgery. It is important to let the surgeon or anaesthetist know that you are being treated with this medicine. It may affect other medicines used during surgery.

Keep follow-up appointments with your doctor and have any tests as directed by your doctor.

It is important to have your follow-up treatments (cycles) of TOMUDEX at the appropriate times to get the optimal result from your treatment.

**Use additional contraception while being given TOMUDEX.**

## **Tell your doctor straight away if you experience:**

- shortness of breath, feel dizzy or lightheaded, experience swelling of the face, tongue, lips, mouth or throat, or itching
- severe pain on eating, drinking or swallowing, or difficulty talking due to ulcers or pain
- severe or persistent diarrhoea during or after treatment
- fever, chills; severe cough or shortness of breath
- any abnormal bruising or bleeding including nosebleeds, bleeding gums, heavy periods, or blood in your stool (poo) or urine (wee)
- discomfort with your infusion site at the time of treatment

## **Things you should not do**

- Do not breastfeed if you are being treated with this medicine.

## **Things to be careful of**

During therapy with TOMUDEX, liver function, kidney function and blood cell counts should be monitored. You should attend all tests as requested by your doctor.

This medicine 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 fluids will contain TOMUDEX and its associated breakdown products for a number of days once you are given TOMUDEX. Body fluids and waste, include blood, urine (wee), stool (poo), vomit and semen.

In general, precautions to protect other people should be taken both while receiving and after treatment as directed by your doctor. Precautions include:

- 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 bag, seal and dispose into the garbage.
- For sexual intercourse, use a barrier method such as a condom.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how TOMUDEX affects you.**

TOMUDEX may cause extreme tiredness, dizziness or light-headedness in some people. If you have these symptoms, do not drive, or or operate machinery which could be dangerous.

## **Drinking alcohol**

No information is available.

## **Looking after your medicine**

TOMUDEX will be stored in the pharmacy or on the hospital ward under the correct conditions.

## **Disposal of TOMUDEX**

The hospital staff will dispose of any leftover TOMUDEX.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Side effects

Side effects	What to do
<ul style="list-style-type: none"><li>• swelling and redness along a vein which is extremely tender when touched</li><li>• loss of appetite, weight loss or constipation</li><li>• nausea, vomiting, swelling of the abdomen, abdominal pain or indigestion, flatulence</li><li>• dehydration (feeling thirsty and/or dry skin)</li><li>• painful or swollen joints, muscle aches and cramps</li><li>• feeling of deep sadness</li></ul>	<b>Speak to your nurse or doctor if you have any of these side effects and they worry you.</b>

Side effects	What to do
<ul style="list-style-type: none"> <li>• insomnia</li> <li>• tingling or numbness of the hands or feet</li> <li>• dizziness</li> <li>• hair loss (thinning), dry, rash and itchy skin, peeling of skin, sweating</li> <li>• red and/or itchy eyes</li> <li>• altered taste</li> <li>• generally feeling unwell, tired or weak</li> <li>• back pain, general pain</li> <li>• hiccups</li> <li>• runny, stuffy or itchy nose</li> <li>• painful urination</li> <li>• swollen ankles, fatigue</li> </ul>	

Side effects	What to do
<ul style="list-style-type: none"> <li>• increased coughing with shortness of breath, wheezing or difficulty breathing, chest pain</li> <li>• diarrhoea</li> <li>• redness, swelling, pain, sore throat, sore or dry mouth, mouth ulcers,</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Side effects	What to do
<p>oral thrush or cold sores, inflammation and/or bleeding in mouth or throat</p> <ul style="list-style-type: none"> <li>• severe nausea and vomiting</li> <li>• painful inflammation and blistering of the digestive tract with risk of bleeding</li> <li>• yellowing of the skin or eyes, dark wee/urine</li> <li>• any unusual bleeding or bruising including nosebleeds, bleeding gums, heavy periods, or blood in your stool (poo) or urine (wee)</li> <li>• fever, chills, infection, low blood pressure, fast heart rate or mental confusion</li> <li>• chest pain</li> </ul>	

**Tell your doctor or nurse as soon as possible if you do not feel well while you are having treatment with TOMUDEX.**

**Diarrhoea and vomiting may be severe and lead to dehydration and kidney issues. Urgent medical attention should be sought as treatment may be changed.**

**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.**

Some of these side effects (for example certain liver conditions, and blood abnormalities) can only be found when your doctor does tests from time to time to check your progress.

Other side effects not listed here may occur in some people.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What TOMUDEX contains

<b>Active ingredient (main ingredient)</b>	raltitrexed
<b>Other ingredients (inactive ingredients)</b>	dibasic sodium phosphate dodecahydrate mannitol sodium hydroxide

**Do not take this medicine if you are allergic to any of these ingredients.**

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

### What TOMUDEX looks like

TOMUDEX is a powder for injection in a vial, which is white to cream coloured solid powder.

TOMUDEX raltitrexed 2mg AUST R 54638

### Who distributes TOMUDEX

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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