

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr TOMUDEX[®]

Raltitrexed for Injection

Read this carefully before you start taking **TOMUDEX** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TOMUDEX**.

What is TOMUDEX used for?

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

How does TOMUDEX work?

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

TOMUDEX works by killing cells within your body which cause certain types of cancer. Your healthcare professional will explain this to you in more detail.

What are the ingredients in TOMUDEX?

Medicinal ingredients: raltitrexed

Non-medicinal ingredients: dibasic sodium phosphate, mannitol, nitrogen and sodium hydroxide

TOMUDEX comes in the following dosage forms:

Powder for solution: 2 mg per vial

Do not use TOMUDEX if:

- you are allergic to raltitrexed or any of the other ingredients of this medicine (see **What are the ingredients in TOMUDEX?**).
- you are pregnant, think you might be pregnant, or are trying to have a baby
- you are breast-feeding
- you have severe kidney and/or liver problems.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TOMUDEX. Talk about any health conditions or problems you may have, including if you:

- have any problems with your blood, kidneys or liver.
- have had radiotherapy (treatment with high dose X-rays).
- are elderly, your healthcare professional will monitor you more closely for side effects. Elderly people can be more affected by the side effects of TOMUDEX.

Other warnings you should know about:

TOMUDEX will be given to you by a healthcare professional who is experienced in giving chemotherapy medicines.

Male and Female Fertility:

- You must **not** get pregnant, or father a child, while you are receiving TOMUDEX and for at least 6 months after your last dose.
- Men and women must use effective birth control while they are receiving TOMUDEX. Talk to your healthcare professional about the birth control options that are right for you.
- If you are a woman who is able to get pregnant you will be given a pregnancy test before starting treatment with TOMUDEX to make sure you are not pregnant.

Driving and Using Machines: TOMUDEX may cause you to feel unwell or weak after you receive it. Your ability to drive or use machinery could be impaired while you have these symptoms. Do not drive or operate machinery until these symptoms have passed.

Blood Tests: TOMUDEX may cause changes to your blood. These occur because of effects on your bone marrow and your liver. Your healthcare professional will take regular blood samples to check your blood.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TOMUDEX:

- vitamins or vitamin supplements
- medicines to thin your blood and stop it from clotting (anti-coagulants).
- Non-steroidal anti-inflammatory drugs (NSAIDs), used to treat pain and inflammation

How to take TOMUDEX:

- 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 healthcare professional. It will depend on your size and how you react to your treatment.

Usual Dose

- Your healthcare professional will calculate your dose from your height and weight.
- Your healthcare professional will need to take regular samples of your blood while you are receiving TOMUDEX. The results of your blood tests will also help the healthcare professional 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.

Overdose:

If you think you, or a person you are caring for, have been given too much TOMUDEX, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using TOMUDEX?

These are not all the possible side effects you may have when taking TOMUDEX. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Loss of appetite
- Indigestion
- Feeling sick (nausea)
- Stomach pain
- Constipation
- Weight loss
- Itchy rash
- Painful joints
- Muscle cramps
- Swollen hands, ankles or feet
- 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)
- Red or peeling skin
- Trouble sleeping (insomnia)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Anemia (low red blood cells): being short of breath, feeling very tired, having pale skin, fast heartbeat, loss of energy, weakness		✓	
Diarrhea		✓	
Mucositis: swelling to the mouth, soreness or ulcers inside your mouth, difficulty swallowing, eating or talking, a dry mouth and lips, bleeding from your bottom, or pain when passing stool		✓	
Neutropenia or Leukopenia (low white blood cells): fever, chills or		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
infection, fatigue, aches and pains, flu-like symptoms			
Vomiting		✓	
COMMON			
Liver problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
Sore throat		✓	
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue, weakness		✓	
UNKNOWN			
Bleeding from the stomach: black or tarry stools, bright red blood in vomit or stools, stomach cramps, dizziness or faintness, feeling tired, paleness, shortness of breath			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

TOMUDEX will be stored by your healthcare professional.

Keep out of reach and sight of children.

If you want more information about TOMUDEX:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

Last Revised DEC 7, 2021