

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **TORISEL**®

Temsirolimus for injection

Read this carefully before you start taking **TORISEL** 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 **TORISEL**.

Serious Warnings and Precautions

TORISEL should be prescribed and managed by a doctor who is experienced in the use of anti-cancer drugs.

Possible serious side-effects with **TORISEL** include:

- Allergic (hypersensitivity/infusion) reactions
- Increased blood glucose levels
- Increased risk of infections
- Interstitial lung disease (chronic inflammation of the lungs)
- Kidney failure

What is **TORISEL used for?**

TORISEL is used in the treatment of metastatic cancer of the kidney. This is when cancer cells have spread from kidney to other parts of the body.

TORISEL is not for use in patients younger than 21 years of age.

How does **TORISEL work?**

TORISEL belongs to a group of medicines called selective inhibitors of mTOR (mammalian target of rapamycin). It blocks tumour cell growth and division.

What are the ingredients in **TORISEL?**

Medicinal ingredient: Temsirolimus

Non-medicinal ingredients:

TORISEL: anhydrous citric acid, dehydrated alcohol, *d,l*-alpha-tocopherol, propylene glycol.

DILUENT for **TORISEL**: dehydrated alcohol, polysorbate 80, polyethylene glycol 400.

****TORISEL** comes in the following dosage forms:**

Solution: 25 mg/mL

Do not use TORISEL if:

- you are allergic (hypersensitive) to temsirolimus, sirolimus or any of the other ingredients of TORISEL.
- you have moderate or severe liver problems.

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

- are allergic (hypersensitive) to antihistamines (medicines used to treat allergic reactions) or cannot take antihistamines for other medical reasons.
- are allergic (hypersensitive) to sirolimus (used to prevent the body from rejecting transplanted kidneys).
- have diabetes.
- have problems with your heart.
- have QT prolongation (a heart rhythm condition) or a family history of QT prolongation.
- have a personal history of fainting spells.
- have a family history of sudden cardiac death at less than 50 years.
- have electrolyte disturbances (e.g. low blood potassium or magnesium levels) or conditions that could lead to electrolyte disturbances (e.g. vomiting, diarrhea, dehydration).
- have an eating disorder or are following a strict diet.
- have had a recent fever, sweats, chills or infection diagnosed. TORISEL may weaken your immune system and increase your risk of getting an infection.
- have shortness of breath, cough, and fever or any new or worsening respiratory symptoms.
- have kidney problems (in addition to kidney cancer).
- have liver problems.
- have known or suspected lesions of the gastrointestinal tract. TORISEL may cause bowel perforation (hole in the wall of the small intestine or colon). This may lead to death.
- have high cholesterol. TORISEL may increase triglycerides and/or cholesterol. This may require treatment with lipid lowering agents.
- are going to have a surgery, if you have had recent major surgery, or if you still have an unhealed wound following surgery. TORISEL may increase the risk of problems with wound healing.
- are planning to receive any vaccines during treatment with TORISEL, as the vaccination may be less effective. The use of live vaccines and close contact with people who have received live vaccines should be avoided during treatment with TORISEL. Examples of live vaccines include, but are not limited to, vaccines for measles, mumps, rubella, oral polio, BCG, yellow fever, varicella, and TY21a typhoid.
- have bleeding problems and/or are receiving blood thinners. TORISEL may increase the risk of bleeding and/or bleeding in the brain.
- are experiencing muscle pain or weakness.

Other warnings you should know about:

Female patients

Pregnancy and birth control

- If you are pregnant or are thinking about becoming pregnant, there are specific risks you should discuss with your healthcare professional. TORISEL may interfere with the growth and development of an unborn baby.
- Avoid becoming pregnant during treatment with TORISEL. You must use reliable method of birth control during treatment and for 3 months after the last dose of TORISEL.
- Tell your healthcare professional right away if you become pregnant during treatment with TORISEL.

Breast-feeding

- Do NOT breast-feed during treatment with TORISEL. This medicine may interfere with the growth and development of the baby. It is not known if TORISEL passes into breast milk.

Male patients

- If you are a male and have a partner of childbearing potential, talk to your healthcare professional before receiving TORISEL. They will discuss with you the possible dangers of taking TORISEL while effects on the fetus and sperm are unknown.
- You must use reliable method of birth control during treatment and for 3 months after the last dose of TORISEL.
- Tell your healthcare professional right away if your partner becomes pregnant during treatment with TORISEL.

Allergic (hypersensitivity/infusion) reactions

- Treatment with TORISEL can cause serious allergic reactions, including anaphylaxis. In some cases, this has led to death.
- During and after treatment with TORISEL, your healthcare professional will monitor for signs and symptoms of an allergic reaction.

Increased blood glucose levels

- TORISEL may cause increases in blood glucose levels. Your healthcare professional may need to give or change your blood sugar medicine to help control your blood sugar levels.
- Tell your healthcare professional if you are feeling very thirsty or need to urinate more often.

Interstitial lung disease (chronic inflammation of the lungs)

- Interstitial lung disease has been reported in patients treated with TORISEL.
- Before starting treatment, you may need to do tests that check your lung health. For example, lung computed tomography scan or chest radiograph.

Monitoring and lab tests

You will have regular visits with your healthcare professional before and during treatment with TORISEL. They will:

- Measure fasting glucose and lipid levels before starting treatment.
- Do regular follow-up tests (including blood tests) as needed during treatment to monitor your health.

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

Serious Drug Interactions

The following medicines may cause serious side effects when taken in combination with TORISEL:

- 5-fluorouracil (used to treat cancer). Taking TORISEL with this medicine may cause bowel perforation (hole in the wall of the small intestine or colon). In some cases, this has led to death.
- Sunitinib and gemcitabine (used to treat cancer)

The following may also interact with TORISEL:

- protease inhibitors (used in the treatment of HIV) such as indinavir, nelfinavir, ritonavir
- medicines used to treat infections such as:
 - macrolide antibiotics (e.g., clarithromycin, erythromycin)
 - rifampicin used to treat infections
 - antifungals (e.g., itraconazole, ketoconazole, voriconazole), used to treat fungal infections
 - rifabutin used to treat infection in people with HIV
- nefazodone or selective serotonin re-uptake inhibitors used to treat depression
- medicines used to treat epilepsy, including carbamazepine, phenytoin and barbiturates
- medicines used to treat high blood pressure or other cardiovascular problems, such as:
 - angiotensin converting enzyme (ACE)-inhibitors (such as enalapril, ramipril, lisinopril)
 - calcium channel blocker (such as amlodipine)
- St. John's Wort (*Hypericum perforatum*), an herbal medicine used to treat depression and other conditions
- medicines that prolong QT/QTc (part of your heart rhythm)
- cannabidiol (CBD), a cannabis product
- medications that can decrease body's natural defense response to infections, such as corticosteroids
- digoxin, used to treat heart failure.

How to take TORISEL:

TORISEL will always be prepared and given to you by your healthcare professional in a healthcare setting. It is given by infusion into your vein (intravenous infusion).

You may also be given an antihistamine (medicines used to treat allergic reactions) before your dose of TORISEL. It will be given intravenously (into your vein).

Usual dose:

The recommended dose of TORISEL is 25 mg infused over a 30 to 60 minute period once weekly.

Overdose:

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

Missed Dose:

If you are concerned that you may have missed a dose, contact your doctor immediately.

What are possible side effects from using TORISEL?

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

- general feeling of weakness
- swelling due to fluid retention
- pain (including abdominal, back and chest pain)
- fever
- nausea
- anorexia
- diarrhoea
- vomiting
- swelling and sores in the mouth and/or digestive tract
- cough
- low red blood cell count
- sore throat
- joint pain
- abscess
- urinary tract infections
- shortness of breath
- nose bleed
- runny nose
- rash, itching
- nail disorder
- acne, dry skin
- change in the sense of taste, taste loss
- weight loss
- sleeplessness
- high blood pressure
- stomach bloating
- gum inflammation, mouth pain
- redness and swelling of the tissues around the eye
- blood tests which show changes in the way the liver is working
- low levels of phosphate in the blood
- low levels of potassium in the blood which may cause muscle weakness
- upper respiratory infections
- inflammation of the follicles in the skin
- decreased number of white blood cells
- decreased number of lymphocytes
- problems with healing after surgery

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Increased blood glucose levels: Excessive thirst or frequency of urination		✓	
Infection: fever, sweats or chills		✓	
Elevated triglycerides and/or cholesterol: may require treatment with lipid lowering agents		✓	
COMMON			
Allergic (hypersensitivity/infusion) reaction: Swelling or difficulty breathing			✓
Bleeding in the stomach, intestines, lung, or bladder: blood in stools, vomit, or urine; black tarry stools, abdominal cramps, chest pain/difficulty breathing		✓	✓
Interstitial lung disease: Shortness of breath, cough, and fever suggestive of inflammation or infection of the lungs		✓	
Prolongation of QT interval (a heart rhythm condition): Irregular heartbeat, fainting, loss of consciousness, seizures		✓	
Pulmonary embolism (blood clot in the lung): chest pain that may increase with deep breathing, cough, coughing up bloody sputum, shortness of breath			✓
Deep vein thrombosis (blood clot in the deep veins of the leg or arm): swelling, pain, arm or leg may be warm to the touch and may appear red			✓
Pneumonia (infection in the lungs): chest pain when you breathe or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Kidney failure: Decreased urine production, body swelling, fatigue, abdominal pain		✓	
Lesions in the gastrointestinal tract (bowel perforation): Stomach pain, nausea, or blood in the stool		✓	
UNKNOWN			
Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine		✓	
Stevens-Johnson syndrome (SJS) (severe skin rash): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			✓

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:

TORISEL will be stored and managed by healthcare professionals. The information below on how to store TORISEL is meant for your healthcare professional.

- Store in a refrigerator (2°C to 8°C).

- Keep the vial in the outer carton in order to protect from light.
- Keep out of reach and sight of children.
- Do not use this medicine after the expiry date stated on the container.
- Infusion solutions should be used up to 6 hours after dilution, and any unused medicine should be discarded.

If you want more information about TORISEL:

- 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 <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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