

Torisel®

Concentrate for Injection

Temsirolimus

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about TORISEL. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TORISEL against the benefits it is expected to provide.

If you have any concerns about using TORISEL, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this leaflet with the medicine

You may need to read it again.

What Torisel is used for

TORISEL is a selective inhibitor of mTOR (mammalian target of rapamycin) that blocks tumour cell growth and division.

Clinical studies have shown that TORISEL can slow the growth of advanced cancer of the kidney and a cancer of the lymph nodes known as mantle cell lymphoma.

Your doctor may have prescribed TORISEL for another reason.

TORISEL is not recommended for use in children (under the age of 18), as there is not enough information on its effects in this age group.

Ask your doctor if you have any questions why TORISEL has been prescribed for you.

TORISEL is available only with a doctor's prescription. It is not habit-forming.

Before you are given TORISEL

When you must not be given TORISEL

Do not have TORISEL if you have an allergy to temsirolimus or any of the other ingredients in TORISEL.

Signs of allergy include a skin rash, itching, shortness of breath and/or a swollen face, lips, tongue or other parts of the body.

Do not have TORISEL if you have moderate or severe liver disease.

TORISEL may cause your liver problems to worsen.

If you are not sure whether any of the above conditions apply to you, ask your doctor. Do not have TORISEL if you are pregnant or think you are pregnant or you are breast-feeding.

TORISEL may cause harm to your unborn child if taken during pregnancy.

It is not known if TORISEL passes into breast milk or what affect it might have on the baby.

Do not have TORISEL after the expiry date printed on the pack or

if the packaging is torn or shows signs of tampering.

If this is the case, take the pack back to your pharmacist.

If you are not sure whether you should have TORISEL, contact your doctor.

Before you are given TORISEL

You must tell your doctor:

- **If you are allergic to sirolimus.**

The active ingredient in TORISEL is very similar to sirolimus, the active ingredient in RAPAMUNE (a medicine used to prevent organ rejection in patients who have had a kidney transplant). If you have had an allergic reaction after taking RAPAMUNE then you may be at increased risk of having an allergic reaction to TORISEL.

- **If you are allergic to antihistamines or cannot take antihistamines for some other medical reason.**

Before you receive TORISEL you may be given an antihistamine to reduce the chance of having an allergic reaction. It is important that you tell your doctor if you cannot have antihistamines.

- **If you have or have ever had problems with your liver.**

You may need extra tests to check your liver is working properly before you are given TORISEL and periodically thereafter. TORISEL may cause your liver problems to worsen. It is important to tell your doctor if you experience any

yellowing of your skin or eyes (jaundice) or changes in the colour of your urine.

- **If you have or think that you may have diabetes.**

TORISEL may increase blood glucose levels. This may result in the need for an increase in the dose of, or initiation of, insulin and/or oral hypoglycaemic agent therapy. Tell your doctor if you experience any excessive thirst or increased frequency of urination.

- **If you have high blood fat levels (triglycerides)**

TORISEL has been known to increase blood fat levels. If your blood levels are already high your doctor may start you on or increase the dose of, a blood fat lowering drug.

If you have not told your doctors about any of these things, tell them before you start taking TORISEL.

Taking Other Medicines

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

Some medicines and TORISEL may interfere with each other. These include:

- Antibiotics such as rifampicin, clarithromycin, telithromycin and rifabutin
- Antifungal medicines such as ketoconazole and itraconazole
- Epilepsy medicines such as carbamazepine, barbiturates and phenytoin
- Protease inhibitors such as atazanavir, nelfinavir, saquinavir, ritonavir and indinavir, which are used to treat HIV/AIDS
- Medicines used to treat high blood pressure, which are called ACE inhibitors
- Medicines used to treat depression, which are called

selective serotonin reuptake inhibitors (SSRIs)

- Sunitinib, which is used to treat kidney cancer
- Interferon alpha which is used to treat cancer
- St. John's wort.

Your doctor or pharmacist has information on medicines to be careful with or avoid while you are using TORISEL.

How TORISEL is given

Follow all directions given to you by your doctor or pharmacist.

TORISEL will always be prepared and given to you by a doctor or another healthcare professional.

TORISEL is given intravenously (into your vein).

The recommended dose of TORISEL for advanced cancer of the kidney is 25 mg infused over a 30- to 60-minute period once weekly. You may be given an antihistamine before your dose of TORISEL.

The recommended dose of TORISEL for mantle cell lymphoma is 175mg, infused over a 30-60 minute period once weekly for 3 weeks followed by weekly doses of 75mg, infused over a 30-60 minute period.

How long will you receive TORISEL

Your doctor will continue to give you TORISEL for as long as you are receiving some benefit.

Do not stop having TORISEL without first talking to your doctor.

If you miss a dose of TORISEL

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

Overdose

If you are concerned that you may have been given too much TORISEL, tell your doctor immediately.

While you are receiving TORISEL

Things you must do

If you become pregnant while using TORISEL, tell your doctor immediately.

It should not be used while you are pregnant.

Women: before starting TORISEL you must be using effective contraception methods and you must continue contraception for 12 weeks after treatment has stopped. If you are unsure, or think you may have become pregnant, talk to your doctor or pharmacist. Discuss contraceptive options with your doctor.

Men: tell your doctor or pharmacist if your partner intends to become pregnant while you are using TORISEL or shortly after you have stopped receiving TORISEL.

TORISEL may cause birth defects if either the male or female is using it at the time of contraception. It is recommended that you use some kind of birth control while you are receiving TORISEL and for at least 12 weeks after the last dose.

Tell your doctor well in advance of any expected hospitalisation or surgery. If you go to hospital unexpectedly, tell the doctor who admits you that you are using TORISEL.

TORISEL has been associated with abnormal wound healing.

Tell any other doctor, dentist or pharmacist who treats you that you are taking TORISEL.

Tell your doctor you are receiving TORISEL if you also want to be vaccinated.

TORISEL may affect your response to vaccination.

Follow the following hygiene procedures whilst using TORISEL

TORISEL is used to fight cancer, and the breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomit and semen.

In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period by:

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

Things you must not do

Do not stop having TORISEL without first checking with your doctor.

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are taking TORISEL.

All medicines have side effects. Often they are not serious but sometimes they can be. You may need medical treatment if you get some side effects.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing.

Tell you doctor if you experience any of the following:

- General feeling of weakness
- Rash
- Sore, red mouth
- Swelling due to fluid retention
- Nausea
- Loss of appetite

These are the most common side effects of TORISEL.

TORISEL may also cause the following side effects:

- Pain (including abdominal, joint, back and chest pain)
- Fever
- Diarrhoea
- Vomiting
- Cough
- Sore throat
- Infections, including urinary tract infections, upper respiratory tract infections or pneumonia
- Abscess
- Shortness of breath
- Nose bleed
- Runny nose
- Itching
- Nail disorder
- Acne
- Dry skin
- Change in the sense of taste
- Constipation
- Chills
- Gum inflammation

- Conjunctivitis
- Twitching or abnormal heart rhythm
- Increased thirst
- Increased frequency of urination
- High blood sugar
- Abnormal kidney function
- Abnormal liver function
- High blood pressure
- Low levels of potassium in the blood (which may cause muscle weakness)
- Interstitial lung disease
- High cholesterol and triglyceride (blood fat) levels
- Perforation of the bowel
- Impaired healing of wounds
- Cataracts
- Blood disorders
- Blood clots
- Temporary paralysis or weakness of muscles
- Yellowing of skin and eyes (jaundice)

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Product Description

What it looks like

Each carton of TORISEL contains two vials. One vial contains the active ingredient. The other contains the diluent.

Ingredients

The active ingredient is temsirolimus.

The following inactive ingredients are also found in TORISEL:

TORISEL Concentrate for Injection.

- Absolute ethanol
- dl-Alpha-tocopherol
- Propylene glycol
- Citric acid

The diluent contains:

- Polysorbate 80
- Macrogol 400
- Absolute ethanol.

Storage

Keep out of the reach and sight of children.

Store in a refrigerator (2°C-8°C).

Keep the vial in the outer carton in order to protect from light.

Do not freeze.

Do not use this medicine after the expiry date stated on the vial label and carton. The first two numbers indicate the month; the next four numbers indicate the year.

Infusion solutions should be discarded immediately after dilution, and any unused medicine should be discarded.

Manufacturer

TORISEL is supplied in Australia by

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

WEST RYDE NSW 2114

Toll Free Number 1800 675 229

Australian Registration Number:

TORISEL 25mg

AUST R 133125

This leaflet was prepared on

4 May 2011

® Registered Trademark