Medication Information Sheet

temsirolimus (TEM-sir-RO-li-mus)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Torisel ®

Appearance: Colourless solution mixed into larger bags of fluids

What is this medication for?

• For treating certain types of kidney cancer

What should I do before I have this medication?

- Tell your doctor and pharmacist if you have or had significant medical condition(s), especially if you have or had:
 - lung, bleeding or liver problems
 - recent surgeries
 - heart rhythm problems
 - diabetes
 - high cholesterol or triglycerides
 - tumour in the brain or spinal cord
 - taken any blood thinners
 - any allergies
- People with cancer have a higher risk of getting other cancers or developing blood clots. Some cancer medications may increase these risks, especially if used for a long period of time. Discuss any concerns about this medication with your health care team.

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

You will have a blood test to check for hepatitis B before starting treatment. See the <u>Hepatitis B and</u> <u>Cancer Medications</u> pamphlet for more information.

The most updated information sheet version can be found on https://www.cancercareontario.ca/drugs

Additional symptom management information is available from https://www.cancercareontario.ca/symptoms

Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. June 2024

How will this medication affect sex, pregnancy and breastfeeding?

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, becomes pregnant during treatment, or if you are breastfeeding.
- If there is ANY chance that you or your partner may become pregnant, you and your partner together must: ► Use 2 effective forms of birth control at the same time while receiving this drug: Keep using birth control until 3 months after the last dose. Discuss with your healthcare team.
- Do not breastfeed while receiving this drug.
- This medication may affect fertility (ability to get pregnant)

How is this medication given?

- This drug is given by injection into a vein.
- You will be given drug(s) before temsirolimus to prevent a reaction.

What else do I need to know while on this medication?

- DO NOT eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while taking this drug. They may increase the amount of drug in your blood and increase side effects.
- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects.
- Make sure your health care team knows about all your medications (prescription, over-the-counter, herbals and supplements). Check with your health care team before starting or stopping any of them.
- For mild aches and pain or fever:
 - If you feel unwell, take your temperature before taking any medications for pain or fever. They may hide a fever.
 - You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
 - Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding. Talk to your health care team before you start or stop these medications.
 - Talk to your health care team or go to the closest emergency room right away if you have a fever. See the <u>Fever</u> pamphlet for more information.

The most updated information sheet version can be found on https://www.cancercareontario.ca/drugs

Additional symptom management information is available from https://www.cancercareontario.ca/symptoms

Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. June 2024

- If you injure yourself or have surgery, your wounds may take longer to heal or may not fully heal. Check with your health care team before you have any surgery or visit your dentist.
- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.

What are the side effects of this medication?

The following table lists side effects that you may have when getting temsirolimus. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on temsirolimus.

Side effects and what to do	When to contact doctor?
Very Common Side Effects (50 or more out of 100 people)	
 High blood sugar You may feel thirsty and pee more often. Your doctor may check your blood sugar level. You may be advised to change your diet or take medication to treat high blood sugar. Check your blood sugar regularly if you have diabetes. 	Contact your health care team as soon as possible
Increased cholesterol or fat levels in the blood Your doctor may check your cholesterol levels regularly.	Contact your health care team if no improvement or if severe
 Abnormal liver lab tests (may be severe) You may have yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. Talk to your health care team if this happens. Your doctor may monitor your liver regularly with a blood test. 	Contact your health care team if no improvement or if severe
 Abnormal kidney lab tests (may be severe) Signs of a kidney problem include swelling, passing very little or no pee, or new unusual weight gain. If you have these signs, call your health team or go to your closest emergency department. To prevent bladder or kidney problems, drink lots of water or other liquids. Your doctor may ask you to drink at least 6 to 8 cups (2 L) per day on treatment days, unless you have been told otherwise. Your doctor may check your kidney function regularly. 	Contact your health care team if no improvement or if severe

The most updated information sheet version can be found on https://www.cancercareontario.ca/drugs

Additional symptom management information is available from https://www.cancercareontario.ca/symptoms

Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. June 2024

Side effects and what to do	When to contact doctor?
Very Common Side Effects (50 or more out of 100 people)	
 Fatigue (tiredness) Be active and aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. Pace yourself, do not rush. Put off less important activities. Rest when you need to. Eat well and stay hydrated by drinking at least 6 to 8 glasses of water or other liquids every day (unless your doctor told you to drink more or less). Avoid driving or using machinery if you are feeling tired 	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Common Side Effects (25 to 49 out of 100 people)	
Rash; dry, itchy skin (may be severe) Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.	Contact your health care team if no improvement or if severe
To prevent and treat dry skin,	
 Use skin moisturizer. Protect your skin from the sun and the cold. Use sunscreen with UVA and UVB protection and a SPF of at least 30. 	
Mild swelling in arms and legs; puffiness (may be severe)	Contact your health
To help prevent swelling :	care team if no improvement or if severe
Eat a low-salt diet.Avoid tight fitting clothing.	567616
If you have swelling in your legs, keep your feet up when sitting.	

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u> Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. June 2024

Side effects and what to do	When to contact doctor?
Common Side Effects (25 to 49 out of 100 people)	
Mouth sores You may have round, painful, white or gray sores inside your mouth. They can occur on the tongue, lips, gums, or inside your cheeks. In more severe cases they may make it hard swallow, eat or to brush your teeth. They usually last 1 to 2 weeks.	Contact your health care team as soon as possible
To help prevent mouth sores:	
 Take care of your mouth by gently brushing and flossing regularly. Rinse your mouth often. Do not use mouthwashes with alcohol. Instead, try a homemade mouthwash: Mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water. 	
If you have mouth sores:	
 Check with your health care team as soon as you notice mouth or lip sores or if it hurts to swallow. Avoid hot, spicy, acidic, hard or crunchy foods Your doctor may prescribe a mouthwash to relieve mouth sores and prevent infection. See the Mouth Care pamphlet for more information. 	
Nausea and vomiting (generally mild) May occur in hours to days after your treatment.	Contact your health care team if no improvement or if severe
If you have nausea or vomiting:	
 Take anti-nausea medication(s) as prescribed to you by your doctor. Drink clear liquids and have small meals. Get fresh air and rest. Do not eat spicy, fried foods or foods with a strong smell. Limit caffeine (e.g. coffee, tea) and alcohol. Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting. 	
Also see Nausea & Vomiting pamphlet for more information.	
 Low appetite You may not feel like eating or you may lose weight. Try to eat foods that you like and eat small meals throughout the day. You may need to take meal supplements to help keep your weight up. Talk to your health care team if you have a low appetite. See our Loss of appetite pamphlet for more information. 	Contact your health care team if no improvement or if severe

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u> Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors.

Side effects and what to do	When to contact doctor?	
Common Side Effects (25 to 49 out of 100 people)		
Fever, chills, infection You have a fever if your temperature taken in your mouth (oral temperature) is:	Get emergency medical help right away	
 38.3°C (100.9°F) or higher at any time OR 38.0°C (or 100.4°F) or higher for at least one hour. 		
While you are getting chemotherapy treatments:		
 Keep a digital thermometer at home and take your temperature if you feel hot or unwell (for example, chills). Avoid taking medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen) as they may hide a fever. Do not eat or drink anything hot or cold right before taking your temperature. Wash your hands often. Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist. 		
If you have a fever, talk to your health care team or go to the closest emergency room. See our <u>Neutropenia (Low white blood cell count)</u> pamphlet for more information.		
Cough; feeling short of breath You may have cough and feel short of breath without any signs of infection, such as a sore throat or a stuffed nose.	Contact your health care team if no improvement or if severe	
Diarrhea May happen days to weeks after you get your treatment. If you have diarrhea :	Contact your health care team if no improvement or if severe	
 Take anti-diarrhea medication if your health care team prescribed it. Avoid foods or drinks with artificial sweetener (e.g. chewing gum, "diet" drinks), coffee and alcohol. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day. Talk to your health care team if you can't drink 6-8 cups of liquids each day when you have diarrhea. You may need special liquids with salt and sugar, called Oral Rehydration Therapy. See the <u>Diarrhea</u> pamphlet for more information. 		

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u> Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors.

Side effects and what to do	When to contact doctor?	
Common Side Effects (25 to 49 out of 100 people)		
 Unusual bleeding or bruising (may be severe) You may have black stools (poo), cough up blood, blood in your pee, purple or red dots on your skin, or bleeding that will not stop. It may happen in days to weeks after you receive your treatment. It may be due to low platelets (a type of blood cell). Take care of your mouth and use a soft toothbrush. Be careful not to cut or hurt yourself. Check with your doctor before you have any surgeries and before going to see the dentist. See the low platelets pamphlet for more information. 	Get emergency medical help right away	
Salt imbalances It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat.	Get emergency medical help right away	

Side effects and what to do	When to contact doctor?	
Less Common Side Effects (10 to 24 out of 100 people)		
 Pains or cramps in the belly If you have constipation or diarrhea it may be causing the pain in your belly. If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. 	Contact your health care team if no improvement or if severe	
 Constipation To help prevent constipation : Drink more liquids and eat well. Drink at least 6 to 8 cups of liquids each day unless you have been told otherwise. Be Active. Exercise can help to keep you regular. Try to eat more fiber (e.g. fruits with skin, leafy greens and whole grains). If you take opioid pain medication, ask your health care team if eating more fibre is right for you. To help treat constipation : If you have not had a bowel movement in 2 to 3 days you may need to take a laxative. Ask your health care team what to do. 	Contact your health care team if no improvement or if severe	

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u> **Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors.** June 2024

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
See the <u>Constipation</u> Pamphlet for more information.	
 Headache; mild joint, muscle pain or cramps Take your pain medication as prescribed by your doctor. You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you. Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk. Rest often and try light exercise as it may help.] 	Contact your health care team if no improvement or if severe
 Taste changes Eat food that needs less chewing. Taste foods at different temperatures, since the flavor may change. Try different forms of foods, like fresh, frozen or canned. Experiment with non-spicy foods, spices and seasonings. 	Contact your health care team if no improvement or if severe
 Nail changes You may have changes in nail colour, pain or tenderness in the nailbed, swelling of cuticles, or loosening of nails. Will slowly return to normal after treatment ends. Use a moisturizer for nails and cuticles. Avoid nail polish and artificial fingernails until your nails have returned to normal. Wear gloves when doing house chores or gardening. 	Contact your health care team if no improvement or if severe
 Trouble falling asleep This may be caused by one of your medications and may improve once your body gets used to the medication or when your treatment ends. Talk to your doctor if this bothers you. 	Contact your health care team if no improvement or if severe

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u> Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. June 2024

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- fever, itchiness, rash, swollen lips, face or tongue, chest and throat tightness
- pain, swelling and hardening of the vein in an arm or leg.
- trouble breathing, have pain in your chest or cough up blood
- irregular heartbeat, shortness of breath, fainting spells or swelling in your legs, ankles and belly
- sudden, severe pain in your belly or stomach area
- severe muscle pain or weakness and dark-coloured pee
- if you hurt yourself badly (wounds may take longer to heal or may not fully heal)
- seizures

Who do I contact if I have questions or need help?

My cancer health care provider is: _____

During the day I should contact:_____

Evenings, weekends and holidays:_____

Other Notes:

June 2024 Modified "What should I do before I have this medication?" section

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u> **Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors.** June 2024

For more links on how to manage your symptoms go to <u>www.cancercareontario.ca/symptoms</u>.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u> Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. June 2024