

Provincial Health Services Authority

For the Patient: UGINETEV

Other Names: Treatment of advanced neuroendocrine tumours of gastrointestinal origin (Non-Functional) using Everolimus

UGI = **U**ndesignated **G**astro**I**ntestinal

NET = **N**euro**e**ndocrine **t**umours

EV = Everolimus

ABOUT THIS MEDICATION

What is this drug used for?

Everolimus is a drug given to treat neuroendocrine tumours.

How does this drug work?

Everolimus interferes with how cells grow, and helps prevent the growth of new blood vessels from surrounding tissue to a cancer. By doing so, everolimus helps prevent an increase in the number of cancer cells.

INTENDED BENEFITS

- This therapy is being given to destroy and/or limit the growth of cancer cells in your body. This treatment may improve your current symptoms, and delay the onset of new symptoms.
- It may take several treatments before your doctor can judge whether or not this medicine is helping.

TREATMENT SUMMARY

How is this drug given?

- Everolimus is usually given once daily in the morning.
- Everolimus is a tablet taken by mouth, on an empty stomach or after a small fat-free meal.
- It is taken continuously, as long as you are responding to the drug and not having too many side effects, as determined by your doctor.
- Sometimes, everolimus may be given at a lower dose, every other day.
- A dexamethasone mouthwash may be prescribed by the doctor to prevent mouth sores. This mouthwash can be started the first day of everolimus and used for the first 2 to 4 months of treatment. The directions will include to swish and spit out the mouthwash four times a day. Do not each or drink for 1 hour after using the mouthwash.

What will happen when I get my drugs?

- A blood test is done on a regular basis, to monitor the effects of the drug on your body. The dose and frequency of your treatment may change, based on your blood counts and/or other side effects.
- The doctor will review the results of the blood test and meet with you each cycle. If you are to proceed with treatment, the appointment would usually be scheduled for the following day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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Revised

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the drug in your treatment plan.

You doctor will review the risks of treatment and possible side effects with you before starting treatment. The pharmacist will review how to take everolimus and possible side effects with you on the day you first pick up your medication.

SERIOUS SIDE EFFECTS	MANAGEMENT
DURING TREATMENT	
Fever may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day. If you have fever (over 100°F or 38°C by an oral thermometer) plus another sign of infection, call your doctor immediately. Other signs of infection include chills, cough, or burning when you pass urine.
Your white blood cells may decrease during treatment. White blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.	 To help prevent infection: Wash your hands often and always after using the bathroom. Avoid crowds and people who are sick. Call your doctor <i>immediately</i> at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine.
Your platelets may decrease during treatment. Platelets help to make your blood clot when you hurt yourself. When the platelet count is low, you may be more likely to bruise or bleed.	 To help prevent bleeding problems: Try not to bruise, cut, or burn yourself. Clean your nose by blowing gently. Do not pick your nose. Avoid constipation. Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding. Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). For minor pain, try acetaminophen (e.g., TYLENOL®) first, but occasional use of ibuprofen may be acceptable

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SERIOUS SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Sore mouth commonly occurs. Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores or bleeding gums can lead to an infection.	 Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. Make a mouthwash with ½ teaspoon baking soda or salt in 1 cup warm water and rinse several times a day.
	 Try the ideas in Food Ideas to Try with a Sore Mouth*.
Diarrhea may sometimes occur.	If diarrhea is a problem:
	Drink plenty of fluids.
	Eat and drink often in small amounts.
	Avoid high fibre foods as outlined in Food Ideas to Help Manage Diarrhea *
	Note: If lactose in milk usually gives you diarrhea, the lactose in the tablet may be causing your diarrhea. Take LACTAID® tablets just before your everolimus dose.

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Nausea and vomiting may occur after your treatment. Most people have little or no nausea.	You may be given a prescription for antinausea drug(s) to take at home. It is easier to prevent nausea than treat it once is has occurred, so follow directions closely. • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in the Practical Tips to Help Manage Nausea*
Skin rashes, dryness, or itchiness may sometimes occur.	If itching is very irritating, call your doctor. Otherwise, be sure to mention it at your next visit.

OTHER SIDE EFFECTS DURING TREATMENT	MANAGEMENT
Minor bleeding, such as nosebleeds , may sometimes occur.	Sit up straight and tip your head slightly forward. Tilting your head back may cause blood to run down your throat.
	 Pinch your nostrils shut between your thumb and forefinger or apply firm pressure against the bleeding nostril for 10 full minutes.
	 After 10 minutes, check to see if your nose is still bleeding. If it is, hold it for 10 more minutes.
	 Stay quiet for a few hours and do not blow your nose for at least 12 hours after the bleeding has stopped.
	Get emergency help if a nosebleed lasts longer than 20 minutes.
Headache may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Muscle or joint pain may sometimes occur.	You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day. Tell your doctor if the pain interferes with your activity.
Sugar control may be affected.	Check your blood sugar regularly if you are diabetic.
Swelling of hands, feet, or lower legs may	If swelling is a problem:
sometimes occur if your body retains extra fluid.	Elevate your feet when sitting.
	Avoid tight clothing.
Taste alteration may sometimes occur.	Try the ideas in Food Ideas to Cope with Taste and Smell Changes.*
Loss of appetite and weight loss sometimes occur.	Try the ideas in Food Ideas to Help with Decreased Appetite.*
Fatigue (tiredness) and lack of energy may commonly occur.	 Do not drive a car or operate machinery if you are feeling tired.
	Try the ideas in Your Bank to Energy Savings: How People with Cancer Can Handle Fatigue.*
Increase in cholesterol or triglycerides (one	Discuss this with your doctor if you have:
of the types of fat in the blood) may sometimes occur.	A history of heart disease.
	High blood pressure.
	High cholesterol or triglycerides.
	You may need to have your cholesterol level checked prior to starting and periodically after starting everolimus.
Hair loss does not occur with everolimus.	Starting everoninus.
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^{*}Please ask your chemotherapy nurse, pharmacist, or dietitian for a copy

INSTRUCTIONS FOR THE PATIENT

- Tell your doctor if you have ever had an unusual or **allergic reaction** to everolimus, sirolimus, or temsirolimus before taking everolimus.
- It is important to take everolimus exactly as directed by your doctor. Make sure you
 understand the directions. Everolimus should be taken at about the same time each day,
 preferably in the morning. You may take everolimus on an empty stomach or after a small fatfree meal.
- Do not chew or crush everolimus tablets. Swallow whole.
- If you miss a dose of everolimus, take it as soon as you can if it is within six hours of the
 missed dose. If it is more than six hours since your missed dose, skip the missed dose and go
 back to your usual dosing times.
- If you vomit the dose of everolimus within 1 hour of taking it, do not take a second dose. Call your doctor during office hours for advice. You will be told whether you need to take another dose.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of everolimus.
- Everolimus may damage sperm and may harm the baby if used during pregnancy. It is best to
 use birth control while being treated with everolimus and at least 8 weeks after stopping
 treatment. Tell your doctor right away if you or your partner becomes pregnant. Do not
 breastfeed during treatment.
- Store everolimus tablets out of the reach of children, at room temperature, away from heat, light, and moisture.
- Tell doctors, dentists, and other health professionals that you are being treated with everolimus before you receive any treatment from them, including vaccinations.
- If you are planning to have surgery, tell your surgeon that you are receiving everolimus. You may need to stop receiving everolimus prior to surgery and restart it only after your doctor says your wounds have healed.

Medication Interactions

Other drugs such as ketoconazole (NIZORAL®), erythromycin (ERYTHROCIN®), and ramipril (ALTACE®) may **interact** with everolimus. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed.

Check with your doctor or pharmacist before you start taking any other drugs.

Avoid grapefruit and grapefruit juice for the duration of your treatment, as these may interact with everolimus.

THE FOLLOWING INFORMATION IS VERY IMPORTANT

STOP TAKING EVEROLIMUS AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **allergic reaction** (rare) soon after a treatment including flushing, face swelling, chest pain or breathing problems.
- Signs of an **infection** such as fever (over 100°F or 38°C by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.

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- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin; extensive bruising.
- Signs of **heart or lung problems** such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, or fainting.

SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of anemia such as unusual tiredness or weakness.
- Signs of **kidney problems** such as lower back or side pain, swelling of feet or lower legs.
- Numbness or tingling in feet or hands.
- Increased **sore throat or mouth** that makes it difficult to swallow comfortably.
- Eye pain or swelling.

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Uncontrolled nausea, vomiting, or diarrhea.
- Headache or other pain not controlled with acetaminophen (e.g., TYLENOL®).
- Easy bruising or minor bleeding.
- Redness, swelling, pain, or sores on your lips, tongue, mouth, or throat.
- Skin rash or itching.
- Cough.
- For diabetics: Uncontrolled blood sugars.

If you experience symptoms or changes in your body that have not been described above but worry you, or if any symptoms are severe, contact:		
at telephone number:		

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