



Provincial Health Services Authority

For the Patient: Sonidegib
Other names: ODOMZO®

- **Sonidegib** (soe" ni deg' ib) is a drug that is used to treat some types of cancer. It is a capsule that you take by mouth. The capsule contains lactose.
- Tell your doctor if you have ever had an unusual or **allergic reaction** to sonidegib before taking sonidegib.
- Before receiving sonidegib you will be **registered** with the ODOMZO® Pregnancy Prevention Program, a distribution control program run by the manufacturer of sonidegib.
- **Blood tests** may be taken regularly during treatment. The dose and timing of your treatment may be changed based on the test results and/or other side effects.
- If you are a woman and are able to bear children, a blood test to determine whether you are **pregnant** will be taken before starting sonidegib treatment, every month during treatment (including dose interruptions), and for 20 months after you stop treatment.
- Sonidegib may harm the baby if used during pregnancy. Severe birth defects to the unborn baby may occur. **Two** forms of reliable **birth control** must be used at the same time during treatment and for 20 months after your last dose. Tell your doctor right away if you become pregnant. Do not breastfeed during treatment and for 20 months after your last dose.
- **Men** who are taking sonidegib must use a condom with spermicide every time they have sex with a female partner who is able to bear children. A condom must be used during treatment (including dose interruptions), and for at least 6 months after your last dose of sonidegib. This is because the drug may be present in semen. **Do not donate semen** while you are taking sonidegib and for at least 6 months after your last dose. Tell your doctor right away if your partner becomes pregnant.
- Sonidegib may affect **fertility** in women. If you plan to have children, discuss this with your doctor before being treated with sonidegib.
- **Do not donate blood** while you are taking sonidegib and for 20 months after your last dose of sonidegib.
- It is important to **take** sonidegib exactly as directed by your doctor. Make sure you understand the directions.

- **Take** sonidegib on an empty stomach.
- If you **miss a dose** of sonidegib, skip the missed dose and go back to your usual dosing times. Do NOT take a double dose to make up for the missed dose.
- If you **vomit** the dose of sonidegib within 1 hour of taking it, do NOT take a second dose. Skip the missed dose and go back to your usual dosing times. Call your doctor during office hours for advice as a medication to prevent nausea may be required for future doses.
- Other drugs such as ketoconazole (NIZORAL®) and rifampin (RIFADIN®) may **interact** with sonidegib. 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 or stop taking any other drugs.
- **Avoid grapefruit and grapefruit juice** for the duration of your treatment, as these may interact with sonidegib.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of sonidegib.
- **Store** sonidegib capsules 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 sonidegib before you receive any treatment from them.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

SIDE EFFECTS	MANAGEMENT
Nausea and vomiting may occur. 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 it has occurred , so follow directions closely. <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea</i>.*
Tiredness and lack of energy may sometimes occur.	<ul style="list-style-type: none"> • Do not drive a car or operate machinery if you are feeling tired. Try the ideas in <i>Fatigue/Tiredness – Patient Handout</i> .*

SIDE EFFECTS	MANAGEMENT
Taste alteration commonly occurs.	Try the ideas in <i>Food Ideas to Cope with Taste and Smell Changes</i> .*
Muscle or joint pain and muscle spasms commonly occur.	<ul style="list-style-type: none"> • You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day for mild to moderate pain. • Drink plenty of fluids. Tell your doctor right away if the pain interferes with your activity. Otherwise, be sure to mention it at your next visit.
Diarrhea may sometimes occur.	If diarrhea is a problem: <ul style="list-style-type: none"> • Drink plenty of fluids. • Eat and drink often in small amounts. • Avoid high fibre foods as outlined in <i>Food Choices to Help Manage Diarrhea</i>.* • Note: If lactose in milk usually gives you diarrhea, the lactose in the capsule may be causing your diarrhea. Take LACTAID® tablets just before your sonidegib dose.
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.
Sugar control may sometimes be affected in patients with diabetes.	Check your blood sugar regularly if you are diabetic.
Loss of appetite and weight loss may sometimes occur.	Try the ideas in <i>Food Ideas to Help with Decreased Appetite</i> .*
Skin rashes may rarely occur.	<ul style="list-style-type: none"> • If itching is very irritating, call your doctor. Otherwise, be sure to mention it at your next visit.
Hair loss is common and may begin within a few days or weeks of treatment. Your hair may thin or you may lose it completely. Your scalp may feel tender. Hair loss may occur on your face and body. Hair will grow back once your treatments are over and sometimes between treatments. Colour and texture may change.	Refer to <i>Resources for Hair Loss and Appearance Changes – Patient Handout</i> .* You may also want to: <ul style="list-style-type: none"> • Apply mineral oil to your scalp to reduce itching. • If you lose your eyelashes and eyebrows, protect your eyes from dust and grit with a broad-brimmed hat and glasses.

***Please ask your nurse or pharmacist for a copy.**

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

- 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.
- Severe unexplained **muscle** pain, muscle swelling or weakness.
- **Urine** that is brown, red, or tea-coloured, passing urine less often, lower back or side pain, swelling of feet or lower legs.

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

- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- Signs of **skin changes** such as a new wart, a sore or reddish bump that bleeds or does not heal, or a change in size, shape, or colour of a mole.

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

- Numbness or tingling in feet or hands.
- Abnormal menstrual bleeding.
- Feelings of sadness that are not usual for you.
- Dizziness.
- Dry mouth or feeling thirsty.
- Dry eyes.
- Abdominal pain.
- Upset stomach.
- Constipation.
- Tender or sore muscles that don't go away.
- Changes in how often you pass urine (go pee).
- For patients with diabetes: uncontrolled blood sugars.

REPORT ADDITIONAL PROBLEMS TO YOUR DOCTOR
