Sonidegib (Odomzo®)

Pronounced: seh-NEH'-deh-gib

Classification: Hedgehog Pathway Inhibitor

About Sonidegib (Odomzo®)

Sonidegib is a type of targeted therapy called a "Hedgehog pathway inhibitor." This means it works by targeting a pathway (series of signals or events) that drives cancer growth. Disrupting the Hedgehog signal prevents the cancer from growing.

How to Take Sonidegib

Sonidegib comes in a capsule and should be taken on an empty stomach. You should take the medication at least 1 hour before, or 2 hours after eating to assure your stomach is empty. The capsule should be swallowed whole; do not break, open or chew the capsule. If you miss a dose, skip the missed dose and take your next dose at the usual time. Do not take 2 doses at once to make up for a missed dose.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

Certain medications, including modafinil, nafcillin, carbamazepine, phenytoin, phenobarbital, ketoconazole, and other azole antifungals, rifampin, certain antiretroviral therapies for HIV and St. John’s Wort can interfere with blood levels of sonidegib. Make sure your provider is aware of all the medications, vitamins, and supplements you are taking.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Sonidegib is available through select specialty pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for the distribution of this medication and shipment directly to your home.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

Possible Side Effects of Sonidegib
There are a number of things you can do to manage the side effects of sonidegib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Kidney Problems**
This medication can cause kidney problems, including an increased creatinine level, which your oncology care team may monitor for using blood tests. Notify your healthcare provider if you notice decreased urine output, blood in the urine, swelling in the ankles, or loss of appetite.

**Muscle Problems**
Muscle spasms and pain are common when taking this medication. However, these can also be a symptom of a serious muscle condition called rhabdomyolysis. This condition is caused by injury to the muscles and can lead to kidney failure. Notify your care team right away if you develop any new or worsening muscle spasms, pain or tenderness, dark urine, or a decreased amount of urine while taking this medication.

**Loss or Thinning of Scalp and Body Hair (Alopecia)**
Your hair may become thin, brittle, or may fall out. This typically begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats, and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

**High Blood Sugar**
This medication can cause elevated blood sugar levels in patients with and without diabetes. Your oncology care team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the healthcare team.

**Pancreas problems**
Bloating, indigestion, fatty stools, loss of appetite, sweating, abdominal pain, and weight loss can all be symptoms of pancreatitis (inflammation of the pancreas). Notify your care provider if you have any of these symptoms.

**Fatigue**
Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Nausea and/or Vomiting**
Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Diarrhea**
Diarrhea can lead to serious dehydration. Call your care team if you experience dizziness, light-headedness, fainting, or muscle cramps, as these can be signs of dehydration.

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of
wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**Low Red Blood Cell Count (Anemia)**

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing, or pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Decrease in Appetite and Taste Changes**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

**Low White Blood Cell Count (Leukopenia or Neutropenia)**

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

**Tips to preventing infection:**

- **Washing hands**, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever, or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

**Blood & Sperm Donation**

Patients should not donate blood while receiving sonidegib and for at least 20 months after stopping the medication. Men should not donate sperm while receiving this medication and for at least 8 months after the final dose.

**Reproductive Concerns**

Exposure of an unborn child to this medication could cause severe birth defects.

- Women should have a negative pregnancy test obtained before starting the medication. Women should not become pregnant while on therapy and for at least 20 months after the last dose. Effective birth control is necessary during treatment, even if your menstrual cycle stops.
- Women should not breastfeed while on treatment or for 20 months after the last dose of this medication.
- This medication can cause a woman’s menstrual cycle to become irregular or stop permanently. As a result, women may experience menopausal effects including hot flashes and vaginal dryness.
• Men should not father a child while on this medication and for at least 8 months after the last dose. Men should always use a condom (even if you have had a vasectomy) to protect your partner from exposure to the medication— or yourself if your partner is taking the medication. Effective birth control is necessary during treatment, even if you believe you are not producing sperm (sterile).
• You may want to consider sperm banking or egg harvesting if you may wish to have a child in the future. Talk about these options with your oncology team.