

Sonidegib (Odomzo)

About This Drug

Sonidegib is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Pain in your abdomen
- Tiredness
- General pain
- Weight loss
- Decreased appetite (decreased hunger)
- Bone and muscle pain
- Muscle spasm
- Changes in the way food and drinks taste
- Headache
- Hair loss. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.
- Itching

Note: The side effects above were reported in 10% or greater of patients treated with sonidegib. Not all possible side effects are included above.

Warnings and Precautions

- Muscle problems and rhabdomyolysis - damage to your muscles which may release proteins in your blood and affect how your kidneys work, which may be life-threatening. You may have severe muscle weakness and/or pain, or dark urine.

Important Information

- Do not donate blood during your treatment and for at least 20 months after treatment.



- Men should not donate sperm during your treatment and for at least 8 months after treatment because this drug is present in semen and may cause harm to a baby.
- Let your doctor know right away if you think you may be pregnant or may have impregnated your partner during treatment. Report any pregnancy to Sun Pharmaceutical Industries, Inc. at 1-800-406-7984.

How to Take Your Medication

- Swallow the medicine whole on an empty stomach, at least 1 hour before you eat or 2 hours after you eat.
- **Missed dose:** If you miss a dose, take your next dose at the regular time, and contact your doctor. Do not take 2 doses at the same time and do not double up on the next dose.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medication label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- To help with weight loss, drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages, milkshakes, and nutritional supplements) instead of water.



- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Taking good care of your mouth may help food taste better and improve your appetite.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day. Avoid coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your nurse and they can help you get in touch with programs in your local area.
- To help with itching, moisturize your skin several times a day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.

Food and Drug Interactions

- This drug may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known drug interactions with sonidegib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This drug may interact with St. John's Wort and may lower the levels of the drug in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Headache that does not go away
- Tiredness that interferes with your daily activities
- Pain in your abdomen or general pain that does not go away or is not relieved by prescribed medicine
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Unexplained muscle spasms, pain, tenderness or weakness
- Signs of rhabdomyolysis such as decreased or very dark urine, muscle pain in the shoulders, thighs, or lower back; muscle weakness or trouble moving arms and legs.
- Itching that is bothersome
- If you think you are pregnant or if you have impregnated your partner



Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 20 months after stopping treatment. Men with female partners of childbearing potential should use condoms, even after a vasectomy, during your cancer treatment and for at least 8 months after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 20 months after stopping treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In women, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on egg banking.

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