

**MEDICATION GUIDE**  
**ODOMZO® (o-DOM-zo)**  
(sonidegib)  
capsules

**What is the most important information I should know about ODOMZO?**

**ODOMZO can cause your baby to die before it is born (be stillborn) or cause your baby to have severe birth defects.**

**For females who can become pregnant:**

- You should talk to your healthcare provider about the risks of ODOMZO to your unborn child.
- Your healthcare provider will do a pregnancy test before you start taking ODOMZO.
- In order to avoid pregnancy, you should use birth control during treatment, and for at least 20 months after your final dose of ODOMZO. Talk to your healthcare provider about what birth control method is right for you during this time.
- Talk to your healthcare provider right away if you have unprotected sex or if you think your birth control has failed.
- Tell your healthcare provider right away if you become pregnant or think that you may be pregnant.

**For males:**

- It is not known if ODOMZO is present in semen. Do not donate semen while you are taking ODOMZO and for at least 8 months after your final dose.
- You should always use a condom, even if you have had a vasectomy, during sex with female partners who are pregnant or who are able to become pregnant, during treatment with ODOMZO and for at least 8 months after your final dose to protect your female partner from being exposed to ODOMZO.
- Tell your healthcare provider right away if your partner becomes pregnant or thinks she is pregnant while you are taking ODOMZO.

**Exposure to ODOMZO during pregnancy:**

If you think that you or your female partner may have been exposed to ODOMZO during pregnancy, talk to your healthcare provider right away. If you become pregnant during treatment with ODOMZO, you or your healthcare provider should report your pregnancy to Sun Pharmaceutical Industries, Inc. at 1-800-406-7984.

**What is ODOMZO?**

ODOMZO is a prescription medicine used to treat adults with a type of skin cancer, called basal cell carcinoma, that has come back following surgery or radiation or that cannot be treated with surgery or radiation.

It is not known if ODOMZO is safe and effective in children.

**What should I tell my healthcare provider before taking ODOMZO?**

**Before you take ODOMZO, tell your healthcare provider if you:**

- have muscle pain or spasms, or have a history of a muscle disorder called rhabdomyolysis or myopathy
- have any other medical conditions
- **are pregnant or plan to become pregnant.** See “What is the most important information I should know about ODOMZO?”
- **are breastfeeding or plan to breastfeed.** It is not known if ODOMZO passes into your breast milk. Do not breastfeed during treatment and for 20 months after your final dose of ODOMZO. Talk to your healthcare provider about the best way to feed your

baby during this time.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**How should I take ODOMZO?**

- Take ODOMZO exactly as your healthcare provider tells you.
- Take ODOMZO 1 time each day.
- Take ODOMZO at least 1 hour before or 2 hours after a meal.
- If you miss a dose, skip the missed dose. Take your next dose as scheduled.

**What should I avoid while taking ODOMZO?**

- Do not donate blood or blood products while you are taking ODOMZO and for 20 months after your final dose.
- Do not donate semen while taking ODOMZO and for at least 8 months after your final dose.

**What are possible side effects of ODOMZO?**

**ODOMZO can cause serious side effects, including:**

- See **“What is the most important information I should know about ODOMZO?”**
- **Muscle Problems.** Muscle spasms and muscle pain are common with ODOMZO, but can also sometimes be symptoms of serious muscle problems. ODOMZO can increase your risk of muscle pain and, rarely a serious condition caused by injury to the muscles (rhabdomyolysis) that can lead to kidney damage. Tell your healthcare provider right away if you develop any new or worsening muscle spasms, pain or tenderness, dark urine, or decreased amount of urine during treatment with ODOMZO.

Your healthcare provider should do a blood test to check for muscle problems and to check your kidney function before you start taking ODOMZO, during treatment, and if you develop muscle problems.

The most common side effects of ODOMZO include:

- |                      |                                 |               |
|----------------------|---------------------------------|---------------|
| • hair loss          | • change in taste               | • tiredness   |
| • nausea             | • diarrhea                      | • weight loss |
| • decreased appetite | • stomach area (abdominal) pain | • headache    |
| • vomiting           | • itching                       |               |

ODOMZO can cause absence of menstrual periods (amenorrhea) in females who are able to become pregnant. It is not known if amenorrhea is permanent. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of ODOMZO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store ODOMZO?**

- Store ODOMZO at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep ODOMZO and all medicines out of the reach of children.**

**General information about the safe and effective use of ODOMZO**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ODOMZO for a condition for which it was not prescribed. Do not give ODOMZO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ODOMZO that is written for health professionals.

**What are the ingredients in ODOMZO?**

**Active ingredient:** sonidegib

**Inactive ingredients:** colloidal silicon dioxide, crospovidone, lactose monohydrate, magnesium stearate, poloxamer, and sodium lauryl sulfate. The capsule shell contains gelatin, red iron oxide, and titanium dioxide. The black printing ink contains ammonium hydroxide, black iron oxide, propylene glycol, and shellac.

Manufactured for Sun Pharma Global FZE by: Patheon Inc., Mississauga, Ontario L5N 7K9, Canada.

Distributed by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512. For more information, go to [www.odomzo.com](http://www.odomzo.com) or call 1-800-818-4555.

ODOMZO is a registered trademark of Sun Pharma Global FZE.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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