

Selumetinib (Koselugo)

About This Medicine

SELUMETINIB (SEL ue ME ti nib) treats neurofibromatosis, a condition that causes tumors to grow along the nerves. It works by blocking a protein that causes tumor cells to grow and multiply. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Nausea and vomiting (throwing up)
- Pain in your abdomen
- Diarrhea (loose bowel movements)
- Tiredness
- Fever
- Muscle, bone and/or joint pain
- Headache
- Rash and pimple-like rash
- Dry skin and itching
- Inflammation/infection of the tissue around your nails

Note: Each of the side effects above was reported in greater than 40% of people treated with selumetinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Blurred vision or other changes in eyesight such as cataracts (clouding of lens in your eye) and high pressure of the eye can happen. You may have sensitivity to light (photosensitivity). Photosensitivity means that you may become more sensitive to the sun and/or light. Your eyes may water more, mostly in bright light.
- Changes in your heart's ability to pump blood properly
- Severe diarrhea

- Severe rash – you may have a pimple-like rash, or a rash with fluid-filled bumps, or red, itchy patches of skin.
- Increase in creatine phosphokinase (CPK), which can sometimes be the result of muscle inflammation or damage. You may have muscle aching and/or cramping.
- Taking vitamin E with selumetinib may increase your risk of bleeding. Let your care team know if you are taking vitamin E.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

Important Information

- It is important that you notify your care team at the first sign of diarrhea, so they can provide you with anti-diarrheal medicine and give you further instructions. Notify your care team if you are taking anti-diarrheal medicine and your symptoms have not improved or are worsening.

How to Take Your Medicine

- **Capsules:** Swallow the medicine whole with or without food. Do not open, dissolve, or chew capsules. Let your care team know if you have trouble swallowing this medicine.
- **Missed dose:** If you miss a dose, and it is less than 6 hours until your next dose, then skip the missed dose and go back to your normal schedule. If you miss a dose, and it is more than 6 hours until your next dose, take the missed dose. Do not take 2 doses at the same time or extra doses. Do not replace a vomited dose and take your next dose at the regular time.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Do not remove desiccant. Protect from moisture. Keep out of the reach of children and pets.
- **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 medicine 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 care team 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 care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.



- Drink enough fluids to keep your urine pale yellow.
- 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 care team 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 care team about medicine that can lessen or stop your diarrhea.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- Wear dark sunglasses when in the sun or bright lights
- To help with itching and dry skin, moisturize your skin several times a day
- Use a gentle, unscented lotion to keep your hands and feet soft. A cream with 10% or 20% urea may help. Don't rub your hands or feet too much.
- Try not to put your hands or feet in hot water, like baths, showers, or washing dishes. Wear gloves when doing work with your hands. Avoid tight shoes or socks.
- Avoid sun exposure and apply sunscreen routinely when outdoors
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of selumetinib in your body which could make side effects worse.
- Check with your care team 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 medicine interactions with selumetinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking selumetinib as this may lower the levels of the medicine in your body, which can make it less effective.
- There are known interactions of selumetinib with blood thinning medicine such as warfarin. Ask your care team what precautions you should take.

When to Call Your Care Team



Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Headache that does not go away
- Blurred vision or other changes in eyesight
- Flashes of light and/or dark areas in your field of vision, colored dots, or halos
- Sensitivity to light
- Tiredness and/or extreme weakness that interferes with your daily activities
- Trouble breathing
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Pain in your mouth or throat that makes it hard to eat or drink
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Pain in your abdomen that does not go away
- Swelling of the legs, feet or ankles
- Weight gain of 5 pounds in one week (fluid retention)
- Pain that does not go away, or is not relieved by prescribed medicines
- Unexplained muscle pain, tenderness, or weakness
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- Signs of inflammation/infection (redness, swelling, pain) of the tissue around your nails.
- Dry skin or itching that is bothersome
- Painful, red, or swollen areas on your hands or feet
- Numbness and/or tingling of your hands and/or feet
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 1 week after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 1 week after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 1 week after the last dose.

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