







## SELUMETINIB

### Name of your medication

Generic name — selumetinib (SEL-yoo-MEH-tih-nib) Brand name — Koselugo™ (koh-SEL-yoo-goh)

#### Common uses

Selumetinib is used for pediatric patients (2 years of age or older) to treat neurofibromatosis type (NF1) with plexiform neurofibromas that cannot be removed by surgery.

Selumetinib may also be used for other treatments.

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Taking selumetinib as instructed is important to allow your child's treatment to be as effective as possible, so here are some key points to remember.

- Your child's dose is based on many factors, including their height and weight, overall health, and diagnosis.
- ☐ Selumetinib should be taken on an empty stomach (at least 1 hour before or 2 hours after a meal or snack).
- Selumetinib should be taken whole and not crushed, cut, or dissolved. If your child is unable to swallow selumetinib, talk to your child's care provider or pharmacist for possible options.
- ☐ If your child misses a dose of selumetinib, follow these guidelines:
  - Do not have your child take the missed dose if it is less than 6 hours before their next scheduled dose. Simply have your child take the next dose at the regularly scheduled time.
  - Do not have your child take two doses at one time.
  - Be sure to write down if your child misses a dose, and let your care provider know about any missed doses.

#### **Drug and food interactions**

- Selumetinib has many drug interactions. Please inform your child's care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- ☐ Grapefruit or grapefruit juice may interact with selumetinib; have your child avoid eating or drinking these during treatment with selumetinib.
- Selumetinib should be taken on an empty stomach (at least 1 hour before or 2 hours after a meal or snack).
- ☐ Talk with your child's care provider or pharmacist before your child takes new medications or supplements or receives any vaccines.
- Selumetinib capsules contain vitamin E. Excessive intake of vitamin E may increase your child's risk of bleeding. Talk with your child's healthcare provider before giving your child any supplements with vitamin E.









## SELUMETINIB

#### Storage and handling

Handle selumetinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- □ Store selumetinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep selumetinib out of reach of pets or other children.
- Leave selumetinib in the provided packaging until it is ready to be taken.
- ☐ When you, a family member, a friend, or a caregiver needs to give the selumetinib to your child, these steps should be followed:
  - 1. Wash hands with soap and water.
  - 2. Put on gloves to avoid touching the medication.
  - 3. Gently transfer the selumetinib from its package to a small medicine or other disposable cup.
  - 4. Administer the medicine immediately by mouth with water.
  - 5. Remove gloves and do not use them for anything else.
  - 6. Throw gloves and medicine cup in household trash.
  - 7. Wash hands with soap and water.
- A daily pill box or pill reminder **is not** recommended to be used with selumetinib.
- If you have any unused selumetinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of selumetinib.
- If you are traveling, put your selumetinib's packaging in a separate sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

#### Side Effects of Selumetinib

Below are common side effects that have been known to happen in about one-third or more of patients taking selumetinib; these are listed on the left side of this table. Your child **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If your child experiences any side effect you cannot manage or that is not listed here, contact your care provider.

| Possible Side Effect | Management  |
|----------------------|---|
| Hair changes         | Your child may experience hair loss. Your child's hair will grow back after treatment is over. Some people choose to wear scarves, caps, or wigs. A short haircut prior to treatment may help with the stress of hair loss. |
|                      | Changes to your child's hair color may occur during treatment. The hair usually returns to normal after treatment, but for some, the change is permanent.   |









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| Possible Side Effect  | Management  |  |  |  |  |  |  |
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| Rash/dry skin/itching   | If your child gets dry or itchy skin while taking selumetinib,  Keep your child's skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose-fitting clothing.  Avoid using perfumes and cologne as these products may increase rash symptoms.  Avoid being in the heat for long periods of time.  Your provider may recommend an over-the-counter antihistamine or a topical cream.  If your child gets a rash that looks like acne on their face, chest, and upper back while taking selumetinib,  Your doctor may prescribe medication to help prevent or manage the rash.  If they do get a rash, keep the area around the rash clean and dry.  Check with your care provider before using anything to treat it.  Do not use over-the-counter acne treatments, such as benzoyl peroxide or salicylic acid or soaps containing alcohol.  Oatmeal baths and unscented moisturizers may help with itching.  Sunlight can make symptoms worse.  Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to ultraviolet (UV) radiation occurs from 10 am–4 pm.  Wear long-sleeved clothing, with UV protection if possible.  Wear broad-brimmed hats.  Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle.  Use lip balm with at least SPF 30.  If your child's rash or itching continues to worsen, contact your care provider. |  |  |  |  |  |  |
| Changes in electrolytes and other laboratory values including • Increased creatine phosphokinase • Decreased albumin • Increased lipase | Changes in some laboratory values may occur and will be monitored by a simple blood test.  Your child may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem.  More severe changes may occur, which can be a sign of a serious problem.  Notify your care provider if they have any of the following: Shortness of breath Chest discomfort Weakness or fatigue New aches and pains Headaches Dizziness Swelling of the legs or feet Red- or brown-colored urine  |  |  |  |  |  |  |









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| Possible Side Effect                                  | Management  |  |  |  |  |  |  |
|---|---|--|--|--|--|--|--|
| Nausea or vomiting                                    | <ul> <li>Eat and drink slowly.</li> <li>Ensure that your child is drinking water or fluid each day unless your care provider has instructed you to limit your child's fluid intake. Contact your care team for instructions on how much water or fluid your child should drink each day.</li> <li>Eat small, frequent meals throughout the day rather than a few large meals.</li> <li>Eat bland foods; avoid spicy, fried, and greasy foods.</li> <li>Avoid vigorous exercise immediately after eating.</li> <li>Don't lie down immediately after eating.</li> <li>Avoid strong odors.</li> <li>Let your provider know if your child experiences nausea or vomiting. Your provider may</li> </ul>  |  |  |  |  |  |  |
| Abdominal pain  | prescribe medication to help with the nausea or vomiting.  Abdominal pain/discomfort may occur. Report any serious pain or symptoms to your care provider immediately.  |  |  |  |  |  |  |
| Diarrhea (loose and/<br>or urgent bowel<br>movements) | <ul> <li>Monitor how many bowel movements your child has each day.</li> <li>Ensure that your child is drinking water or fluid each day unless your care provider has instructed you to limit your child's fluid intake. Contact your care team for instructions on how much water or fluid your child should drink each day.</li> <li>Eat small, frequent meals throughout the day rather than a few large meals.</li> <li>Eat bland, low-fiber foods, such as bananas, applesauce, potatoes, chicken, rice, and toast.</li> <li>Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains.</li> <li>Avoid foods that cause gas, such as broccoli and beans.</li> <li>Avoid lactose-containing foods, such as yogurt and milk.</li> <li>Avoid spicy, fried, and greasy foods.</li> </ul> |  |  |  |  |  |  |
|   | <ul> <li>Contact your provider if either of the following occurs:</li> <li>The number of bowel movements your child has in a day increases by 4 or more.</li> <li>They feel dizzy or lightheaded.</li> <li>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your child's diarrhea, but talk to your care provider before starting this medication.</li> </ul>  |  |  |  |  |  |  |
| Muscle or joint pain or<br>weakness                   | <ul> <li>Keep a diary of your child's pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts.</li> <li>Have your child stay as active as possible, but know that it is okay to rest as needed.</li> <li>Tell your care provider if pain interferes with their activity.</li> <li>If the pain or weakness bothers them, ask your provider what you may use to help with this discomfort. Use only pain medication that has been prescribed or recommended by your care provider.</li> </ul>  |  |  |  |  |  |  |









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| Possible Side Effect         | Management  |  |  |  |  |  |  |
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| Fatigue                      | <ul> <li>Your child may be more tired than usual or have less energy.</li> <li>Have them stay as active as possible, but know it is okay to rest as needed.</li> <li>Try to have them do some activity every day.</li> <li>Plan their activities, and have them do them at a time of day when they feel a bit more energetic.</li> </ul>  |  |  |  |  |  |  |
| Pyrexia                      | Your child may feel hot, cold and shivery, achy, or dizzy. This usually starts during the first month of therapy but could happen at any time.  • Call your doctor immediately if they have a fever of 100.4°F.  Ask your doctor if they can take medicine to help with the fever.  |  |  |  |  |  |  |
|                              | Ask your provider what you may use to help with this discomfort.  |  |  |  |  |  |  |
| Headache                     | Contact your care provider right away if your child's headache has any of the following characteristics:  • Follows a head injury  • Is severe or starts suddenly  • Does not go away after 3 days  • Is associated with vomiting, visual disturbance, neck stiffness, drowsiness, confusion, rash, weakness in an arm or leg, or numbness; or is made worse by coughing or lowering the head   |  |  |  |  |  |  |
| Nail changes<br>(paronchyia) | Usually, this change starts at the cuticle and may affect the skin around the nail.  Biting, chewing, and picking at the nails can increase the risk of getting an infection.  Talk to your care provider if you notice any changes in your child's nails.  |  |  |  |  |  |  |
| Changes in liver function    | Your child's liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:  • Yellowing of the skin or whites of their eyes  • Dark or brown urine  • Bleeding or bruising   |  |  |  |  |  |  |
| Stomatitis                   | <ul> <li>Practice good mouth care.</li> <li>Rinse your child's mouth frequently.</li> <li>Brush your child's teeth with a soft toothbrush or cotton swab after meals.</li> <li>Use a mild non-alcohol mouth rinse at least 4 times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water.</li> <li>If your child has sores in their mouth, avoid using mouthwashes that contain alcohol.</li> </ul> |  |  |  |  |  |  |
|                              | Call your care provider if your child experiences pain or sores in their mouth or throat.   |  |  |  |  |  |  |









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| Possible Side Effect   | Management  |  |  |  |  |  |  |  |
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| Decreased<br>hemoglobin, the part<br>of the red blood cells<br>that carries iron and<br>oxygen | Your child's hemoglobin should be monitored by a simple blood test. When their hemoglobin is low, you may notice that they get tired or fatigued more easily.  Try to get 7–8 hours of sleep per night.  Stay as active as possible, but know that it is okay to rest as needed.  You might notice that your child becomes more pale than usual.  Let your care provider know right away if they experience any of the following:  Shortness of breath  Dizziness  Palpitations   |  |  |  |  |  |  |  |
| Constipation   | <ul> <li>Monitor how many bowel movements your child has each day.</li> <li>Ensure that your child is drinking water or fluid each day unless your care provider has instructed you to limit your child's fluid intake. Contact your care team for instructions on how much water or fluid your child should drink each day.</li> <li>Stay active and exercise, if possible.</li> <li>Eat foods high in fiber like raw fruits and vegetables.</li> <li>Contact your care provider if your child has not had a bowel movement in 3 or more days.</li> <li>Your care provider may recommend over-the-counter medications to help with their constipation. A daily stool softener such as docusate (Colace®) and/or laxative such as senna (Senokot®) may be helpful. If these do not help within 48 hours, tell your provider.</li> </ul> |  |  |  |  |  |  |  |
| Decreased white<br>blood cells (WBCs)<br>and increased risk for<br>infection                   | Your child's WBCs should be monitored by a simple blood test. When your child's WBCs are low, they are at a greater risk of having an infection. Take the following precautions to protect them from infection.  Have them wash their hands often, especially before eating and after using the bathroom.  Avoid crowds and people with fevers, flu, or other infection.  Bathe regularly to keep good personal hygiene.  Contact your care provider if they experience any signs or symptoms of an infection:  Fever (temperature more than 100.4°F or 38°C)  Chills  Sore throat  Burning with urination  Unusual tiredness  A sore that becomes red, is draining, or does not heal  Check with your care provider before they take any medicine for a fever or chills.   |  |  |  |  |  |  |  |









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#### Serious side effects

| Selumetinib can make your child's heart work harder to pump blood to the rest of their body. Notify your child's care team if |
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| your child is having shortness of breath or chest pain.   |

Selumetinib may be harmful to your child's eyes. Call your child's care team if your child is having any issue with vision or if your child has pain in their eyes.

If your child experiences ANY uncontrolled side effect, call your child's physician or healthcare center immediately:

#### (INSTITUTIONAL CONTACT INFO)

#### Handling body fluids and waste

Since selumetinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once your child has started to take selumetinib, it is important to adhere to the following instructions every day for as long as their treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- ☐ Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- □ Toilet and septic systems
  - Your child may use the same toilet, septic tank, and/or sewer that they usually use. If your child uses a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
  - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
  - · Have your child wash their hands with soap and water after using the toilet.
- ☐ If your child needs a bedpan, be sure the caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If your child does not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- ☐ Wash any skin that has been exposed to body waste or selumetinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- ☐ Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

#### Pregnancy, sexual activity, and contraception

- □ Women should not become pregnant and men should not get a partner pregnant while taking selumetinib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 7 days after the last dose of selumetinib.
- ☐ Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking selumetinib and for 7 days after the last dose of selumetinib.
- ☐ Please inform your care provider if they become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care team for assistance.









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| ☐ Talk with your care provider about the proc   | ess for obtaining your selumetinib.           |
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|   | (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO) |
| Additional resources  |   |
| Product website: https://www.koselugo<br>Product prescribing information: https://alexionones | s://www.azpicentral.com/koselugo/koselugo.pdf |
|   | <b>Updated – March 29, 2023</b>               |
| Additional instructions   |   |
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