

YOUR KOSELUGO® (selumetinib) INFORMATION GUIDE

KOSELUGO, AN ORAL MEDICINE, IS **THE ONLY FDA-APPROVED PEDIATRIC TREATMENT** FOR NF1 PN THAT CANNOT BE COMPLETELY REMOVED BY SURGERY (plexiform neurofibromas [PN] are noncancerous tumors, which are sometimes referred to as plexiform tumors)

Koselugo is a prescription medicine that is used to treat children 2 years of age and older with neurofibromatosis type 1 (NF1) who have plexiform neurofibromas that cannot be completely removed by surgery. It is not known if Koselugo is safe and effective in children under 2 years of age.



**IN A CLINICAL STUDY, KOSELUGO WAS PROVEN TO
SHRINK PLEXIFORM TUMORS IN PEDIATRIC PATIENTS**

66% of patients saw their plexiform neurofibromas shrink by at least 20%

(Learn more on pages 4-6)

IMPORTANT SAFETY INFORMATION

Before taking Koselugo, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have eye problems
- are pregnant or plan to become pregnant. Koselugo can harm your unborn baby
 - Females who could become pregnant and males with female partners who could become pregnant should use effective birth control (contraception) during treatment with Koselugo and for 1 week after your last dose
 - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Koselugo
- are breastfeeding or plan to breastfeed. It is not known if Koselugo passes into your breast milk
 - Do not breastfeed during treatment with Koselugo and for 1 week after your last dose
 - Talk to your healthcare provider about the best way to feed your baby during this time

Please read additional Important Safety Information on pages 8 and 9.
Please see full Prescribing Information, including Patient Information,
by clicking [here](#) or at [Koselugo.com](https://www.koselugo.com).

**Koselugo®**
(selumetinib)
10 mg & 25 mg capsules



WHAT ARE PLEXIFORM NEUROFIBROMAS (PN), OR PLEXIFORM TUMORS?

30%-50%

Plexiform tumors may appear in 30%-50% of children with NF1



PN grow along nerves and can be located anywhere in the body



They can be large or small in size and continue to grow if left untreated

Signs of symptomatic plexiform tumors



PHYSICAL CHANGES

Have a cluster of small lumps formed under your child's skin?

Have you noticed any skin discoloration?

Have any lumps begun to be noticeable under the skin?



DIFFICULTY MOVING

Is your child having difficulty moving any part of their body?

Does your child get tired more often?

Can your child sleep comfortably?

Is your child experiencing any tingling or stinging sensations?



PAIN

Is your child no longer doing their usual activities?

Is your child fussier than usual?

Does your child seem bothered or uncomfortable?



OTHER SYMPTOMS

Is your child having trouble breathing?

Is your child experiencing vision changes or other eye problems?

Is your child having bowel or bladder problems?

Remember—if your child experiences a new plexiform tumor symptom, or if a symptom your healthcare team knows about has gotten worse, report it as soon as possible.



WHY CAN'T SOME PLEXIFORM TUMORS BE COMPLETELY REMOVED WITH SURGERY?

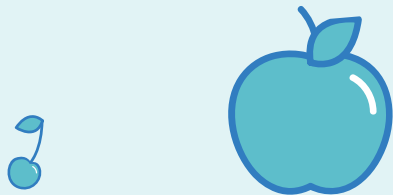
Surgery for NF1 plexiform neurofibromas may not be recommended by your child's healthcare provider. One reason is plexiform neurofibromas may be closely intertwined with critical nerves and located near major organs. Also, PN may not be completely removed by surgery.



PLEXIFORM TUMORS CAN APPEAR IN DIFFERENT SIZES AND LOCATIONS IN THE BODY

A child with NF1 may develop 1 or several plexiform tumors. These tumors can grow on any nerve of the body and can be small or large in size.

PLEXIFORM TUMORS CAN BE SMALL OR LARGE

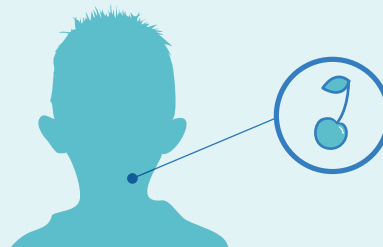


Small plexiform tumor

Large plexiform tumor

Plexiform tumors start small but can grow and become large.

THE LOCATION OF PLEXIFORM TUMORS MAY BE IMPORTANT



Plexiform tumors of any size may cause symptoms. If your child develops a tumor, it may not be able to be completely removed by surgery.

Keeping an eye out for plexiform tumor symptoms can be an important way to help your child during their NF1 journey

IMPORTANT SAFETY INFORMATION (cont'd)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements. Especially tell your healthcare provider if you are taking aspirin, blood thinners, or other medicines to treat blood clots. Koselugo contains vitamin E, which may increase your risk of bleeding.

Koselugo may cause serious side effects, including:

Heart problems. Koselugo can lower the amount of blood pumped by your heart, which is common and can also be severe. Your healthcare provider will do tests before and during treatment with Koselugo to check how well your heart is working. Tell your healthcare provider right away if you get any of the following signs or symptoms:

- persistent coughing or wheezing
- shortness of breath
- swelling of your ankles and feet
- tiredness
- increased heart rate

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(selumetinib)
10 mg & 25 mg capsules



WHAT ARE POSSIBLE SIDE EFFECTS OF KOSELUGO?

Koselugo may cause serious side effects, including:

Heart problems: Koselugo can lower the amount of blood pumped by your heart, which is common and can also be severe. Your child's healthcare provider will do tests before and during treatment with Koselugo to check how well your child's heart is working. Tell your child's healthcare provider right away if your child gets any of the following signs or symptoms:

- persistent coughing or wheezing
- tiredness
- shortness of breath
- increased heart rate
- swelling of your child's ankles and feet

Eye problems: Koselugo can cause eye problems that can lead to blindness. Your child's healthcare provider will check your child's vision before and during treatment with Koselugo. Tell your child's healthcare provider right away if your child gets any of the following signs or symptoms:

- blurred vision
- loss of vision
- dark spots in your child's vision (floaters)
- other changes to your child's vision

Severe diarrhea: Diarrhea is common with Koselugo and can also be severe. Tell your child's healthcare provider right away the first time that your child gets diarrhea during treatment with Koselugo. Your child's healthcare provider may give your child medicine to help control diarrhea and may tell them to drink more fluids.

Skin rash: Skin rashes are common with Koselugo and can also be severe. Tell your child's healthcare provider if your child gets any of the following signs or symptoms:

- rash that covers a large area of your child's body
- blisters • peeling skin

Muscle problems (rhabdomyolysis): Muscle problems are common with Koselugo and can also be severe. Treatment with Koselugo may increase the level of a muscle enzyme in your child's blood, which may be a sign of muscle damage. Your child's healthcare provider should do a blood test to check your child's muscle enzyme levels before they start taking Koselugo and during treatment. Tell your child's healthcare provider right away if your child gets any of the following signs or symptoms:

- muscle aches or pain
- dark, reddish urine
- muscle spasms and weakness

Your child's healthcare provider may change your child's dose, temporarily stop, or permanently ask your child to stop taking Koselugo if they have any of these side effects.



WHAT ARE POSSIBLE SIDE EFFECTS OF KOSELUGO? (cont'd)

The most common side effects of Koselugo are:



Vomiting



Feeling of tiredness, weakness, or lacking energy



Headache



Stomach pain



Muscle and bone pain



Redness around the fingernails



Nausea



Fever



Itching



Dry skin



Inflammation of the mouth

These are not all the possible side effects of Koselugo.

As with any medicine, it's possible to experience side effects while taking Koselugo. Be sure to tell your child's doctor if your child experiences any side effect that bothers them or does not go away.

Remember, the information on this page does not replace medical guidance or directions from your doctor. Always talk to them about side effects and ways to help manage them

IMPORTANT SAFETY INFORMATION (cont'd)

Koselugo may cause serious side effects, including (cont'd):

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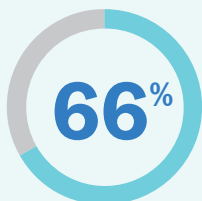
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- loss of vision
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HOW MIGHT KOSELUGO HELP MY CHILD?



- Koselugo has been proven to shrink plexiform tumors in patients with NF1
- In a clinical study, 66% of patients responded to Koselugo, meaning that these patients saw a 20% or more decrease in their tumors' size, confirmed by 3D magnetic resonance imaging scan
- 82% of patients who responded to Koselugo continued to benefit from treatment for at least 1 year

For patients who responded in the clinical study, some had confirmed plexiform tumor shrinkage in as early as 3 months

Of the 33 patients who responded to Koselugo treatment in the clinical trial, about one-half saw their tumor volume shrink by at least 20% within 7.2 months. The time that it took for a response to be seen ranged from 3.3 months to 19.2 months.

The range of patient response in the clinical study



< **Response to Koselugo may occur at different times, so it's important that your child keeps taking their medicine as instructed by their doctor** >



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CHECK YOUR AWARENESS OF PLEXIFORM TUMORS

Plexiform tumors can appear or change at any time in your child's NF1 journey and may show signs outside of a doctor visit. Here are some questions to ask yourself prior to your next visit to your child's doctor.

- *Is my child experiencing symptoms such as pain, fatigue, difficulty moving, vision changes, trouble breathing, or problems with their bowel or bladder?*
- *Have I noticed any physical changes in my child?*
- *Does my child have any small lumps under their skin?*
- *Is my child having difficulty sleeping?*
- *Is my child struggling with their daily activities?*
- *Has my child been experiencing any trouble breathing?*
- *Does my child feel discomfort in any way?*

Sharing the answers with your child's healthcare team can help you have more informative and productive conversations.



NEUROLOGIST

Name: _____

Phone Number: _____

GENETICIST

Name: _____

Phone Number: _____

ONCOLOGIST/TUMOR SPECIALIST

Name: _____

Phone Number: _____

OTHER:

Name: _____

Phone Number: _____

Collaborate with your child's doctor to take an active approach to treatment decision-making

IMPORTANT SAFETY INFORMATION (cont'd)

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INDICATION

What is Koselugo?

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 - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Koselugo
- are breastfeeding or plan to breastfeed. It is not known if Koselugo passes into your breast milk
 - Do not breastfeed during treatment with Koselugo and for 1 week after your last dose
 - Talk to your healthcare provider about the best way to feed your baby during this time

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- peeling skin
- blisters

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- muscle aches or pain
- muscle spasms and weakness
- dark, reddish urine

Your healthcare provider may change your dose, temporarily stop, or permanently ask you to stop taking Koselugo if you have any of these side effects.

The most common side effects of Koselugo are:

- vomiting
- stomach pain
- nausea
- dry skin
- feeling of tiredness, weakness, or lacking energy
- muscle and bone pain
- fever
- inflammation of the mouth
- headache
- redness around the fingernails
- itching

These are not all the possible side effects of Koselugo.

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HELPING YOUR CHILD ACCESS THE CARE THEY NEED

OneSource™ is a free, personalized patient support program offered by Alexion. Whether your child is newly diagnosed or has had their condition for some time, our specialists will be by your side. We can help you make sense of your health insurance coverage, answer questions about your child's treatment with Koselugo, and connect you to community resources.

We're committed to helping your child start and stay on track with their prescribed treatment.



OneSource™ Support Services

Your dedicated Patient Access Navigator is here to guide and give you the support you deserve—whatever your care plan may be. They can:

- Answer questions about neurofibromatosis type 1 (NF1) plexiform neurofibromas (PN), Koselugo, your insurance coverage, and more
- Provide support during treatment
- Help you avoid interruptions in your child's treatment during insurance changes, travel plans, or other life events
- Help you get involved with the rare disease community through events and meetings



Health insurance can be complicated. We're here to help make sense of it all.

OneSource can help by:

- Providing information that explains your insurance coverage for Koselugo
- Addressing financial concerns or gaps in coverage



To learn more or contact your dedicated Patient Access Navigator, please call **1-888-765-4747**, Monday through Friday, 8:30 AM–8 PM ET, or visit www.AlexionOneSource.com.

Ask your doctor if Koselugo is right for your child.
For more information, visit www.Koselugo.com.

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