

KOSELUGO®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking KOSELUGO?

KOSELUGO contains the active ingredient selumetinib. KOSELUGO is used to treat paediatric patients (2 years and above) who have NF1 and a type of tumour (symptomatic plexiform neurofibromas) that cannot be completely removed by surgery.

For more information, see Section [1. Why am I using KOSELUGO?](#) in the full CMI.

2. What should I know before I take KOSELUGO?

Do not use if you have ever had an allergic reaction to KOSELUGO or any of the ingredients listed at the end of the CMI or if you have severe liver disease.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take KOSELUGO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KOSELUGO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take KOSELUGO

- Take KOSELUGO twice a day, about 12 hrs apart. Your doctor will tell you how much to take based on your height and weight
- Swallow the capsules whole with water on an empty stomach. Do not chew, dissolve or open the capsules.

More instructions can be found in Section [4. How do I use KOSELUGO?](#) in the full CMI.

5. What should I know while taking KOSELUGO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist
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	<p>you visit that you are taking KOSELUGO</p> <ul style="list-style-type: none"> • Use effective contraception to avoid becoming pregnant (see Section 5 in the full CMI)
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine or change the dose unless your doctor tells you to • Do not become pregnant • Do not give to child younger than 2 years of age and do not chew, dissolve or open the capsules
Call your Doctor straight away	<ul style="list-style-type: none"> • If you experience any of the serious side effects listed in Section 6 in the full CMI. • If you become pregnant while using KOSELUGO
Driving or using machines	<ul style="list-style-type: none"> • Avoid driving or using machines if you feel tired or if you have problems with your vision
Looking after your medicine	<ul style="list-style-type: none"> • KOSELUGO capsules should be kept in the original bottle

- Keep KOSELUGO in a cool dry place where the temperature stays below 30°C

For more information, see Section [5. What should I know while using KOSELUGO?](#) in the full CMI.

6. Are there any side effects?

Call your doctor straight away if you notice any of these serious side effects: blurred vision, loss of vision, dark spots in your vision or other changes to your vision, persistent coughing and wheezing, shortness of breath, swelling of ankles/feet, tiredness, increased heart rate, diarrhoea, muscle aches or pains, muscle spasms and weakness, dark or reddish urine, rash that covers a large area of your body, blisters or peeling.

Speak to your doctor if you have any of these most common side effects: vomiting, stomach pain, nausea, inflammation of the mouth, headache, redness around the fingernails, dry skin, rash, tiredness/ weakness/ lacking energy, muscle and bone pain, fever, itching. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

KOSELUGO®

Active ingredient(s): *selumetinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking KOSELUGO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KOSELUGO.**

Where to find information in this leaflet:

- [1. Why am I taking KOSELUGO?](#)
- [2. What should I know before I take KOSELUGO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take KOSELUGO?](#)
- [5. What should I know while taking KOSELUGO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking KOSELUGO?

KOSELUGO contains the active ingredient selumetinib. Selumetinib is a type of medicine called a 'MEK inhibitor', it works by blocking certain proteins which are known to be involved in the growth of tumour cells. KOSELUGO may reduce the size of tumours that grow along nerves called Plexiform Neurofibromas (PNs). The tumours are caused by a genetic condition called Neurofibromatosis Type 1 (NF1).

KOSELUGO is used to treat paediatric patients aged 2 years and above with NF1, who have symptomatic plexiform neurofibromas that cannot be completely removed by surgery.

2. What should I know before I take KOSELUGO?

Warnings

Do not take KOSELUGO if:

- you are allergic to selumetinib, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- you have severe liver disease
- you are pregnant or intend to become pregnant
- you are breastfeeding

KOSELUGO should not be given to children below 2 years of age.

Check with your doctor if you:

- think you might have difficulties swallowing the capsules whole
- take any medicines for any other condition
- take supplemental vitamin E (including multivitamins that contain vitamin E)
- have any other medical conditions, especially the following:
 - eye problems
 - heart problems

KOSELUGO can cause eye problems. Tell your doctor as soon as possible if you get blurred vision or any other changes to your sight during treatment. Your doctor should examine your eyes if you have any new or worsening problems with your sight while you are taking KOSELUGO.

KOSELUGO can lower the amount of blood pumped by your heart. Your doctor should do tests before and during your treatment with KOSELUGO to check how well your heart can pump blood.

KOSELUGO capsules contain vitamin E that may make you bleed more easily. This means you should tell your doctor if you take other medicines that increase your risk of bleeding such as:

- aspirin
- blood thinners such as warfarin or other medicines for blood clots

- supplements that include vitamin E (including multivitamins that contain vitamin E)

KOSELUGO may increase the level of an enzyme in your blood called creatine phosphokinase (CPK) and may be a sign of muscle damage. Your healthcare provider should do a blood test to check your blood levels of CPK before you start taking KOSELUGO and during treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Talk to your doctor before taking KOSELUGO if you are pregnant, think you may be pregnant or are planning to have a baby. This is because KOSELUGO may harm an unborn child. You may be asked by your doctor to take a pregnancy test before starting treatment. If you are pregnant, you should not take KOSELUGO. You should not become pregnant while taking this medicine.

Female patients: If you are able to become pregnant you should use effective contraception while you are taking KOSELUGO and for at least 1 week after the last dose. It is not known whether KOSELUGO may interfere with how well hormonal contraceptives work. Please tell your doctor if you are taking a hormonal contraceptive, as your doctor may recommend the addition of a non-hormonal method of birth control. If you do become pregnant during treatment, tell your doctor straight away.

Before you start taking KOSELUGO, tell your doctor if you are breastfeeding. For the safety of your baby, you should not breastfeed during treatment with KOSELUGO

Male patients: You should use effective contraception while you are taking KOSELUGO and for 1 week after the last dose. If your partner becomes pregnant during your treatment with KOSELUGO, tell your doctor straight away

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines can affect the levels of KOSELUGO in your body. Also, KOSELUGO can affect the way some other medicines work. Tell your doctor if you are taking medicines that contain any of the following:

- Clarithromycin or erythromycin used to treat bacterial infections
- Carbamazepine or phenytoin used to treat seizures and epilepsy
- Fluconazole, itraconazole or ketoconazole used to treat fungal infections
- Rifampicin used to treat tuberculosis (TB)
- St. John's wort (*Hypericum perforatum*), a herbal product, used to treat depression and other conditions
- Fluoxetine used to treat depression and other mental disorders

- Ticlopidine used to thin your blood and prevent clotting
- Omeprazole used to treat heartburn

KOSELUGO may make you bleed more easily. This means you should tell your doctor or other healthcare professional you visit if you take other medicines that increase your risk of bleeding such as:

- aspirin
- blood thinners such as warfarin or other medicines for blood clots
- supplements that include vitamin E (including multivitamins that contain vitamin E)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KOSELUGO.

4. How do I take KOSELUGO?

How much to take

- the doctor will calculate the correct dose to use and tell you which and how many capsules of KOSELUGO to take. The amount you should take depends on your body surface area, which is measured in square metres (m²), and is worked out by the doctor from your height and weight.
- your doctor may prescribe a lower dose if:
 - you have problems with your liver (hepatic impairment)
 - you have certain side effects while you are taking KOSELUGO

- your doctor may lower your dose or stop treatment, either for a short time or permanently
- Follow the instructions provided and use KOSELUGO until your doctor tells you to stop.

When to take KOSELUGO

- Take KOSELUGO twice a day, about 12 hours apart
- Doses should be taken on an empty stomach (at least 1 hour before a meal or 2 hours after a meal). This means that:
 - after taking KOSELUGO, you must wait at least 1 hour before eating, or
 - after eating, you must wait at least 2 hours before taking KOSELUGO

How to take KOSELUGO

- swallow KOSELUGO capsules whole with water.
- do not chew, dissolve, or open the capsules
- If you have, or think you might have difficulty swallowing capsules whole, talk to your doctor before starting treatment

If you are sick

If you vomit at any time after taking KOSELUGO, do not take an additional dose. Take the next dose as scheduled.

If you forget to take KOSELUGO

What to do if you forget to take a dose of KOSELUGO depends on how long it is until your next dose:

- if it is more than 6 hours until your next dose: Take the missed dose as soon as you remember. Then take the next dose at the normal time
- if it is less than 6 hours until your next dose: Skip the missed dose. Then take the next dose at the normal time

Do not take a double dose (two doses at the same time) to make up for forgotten individual doses.

If you stop taking KOSELUGO

Do not stop taking KOSELUGO unless your doctor tells you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you take too much KOSELUGO

If you think that you have taken too much KOSELUGO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking KOSELUGO?

Things you should do

- if you are about to be started on any new medicine or supplements remind your doctor and pharmacist that you are taking KOSELUGO.
- if you are about to have any blood tests, tell your doctor that you are taking this medicine.
- keep all of your doctor's appointments so that your progress can be checked.
- use effective contraception to avoid becoming pregnant while being treated with KOSELUGO (see Section 2)
- tell your doctor if you cannot swallow the capsule whole

Call your doctor straight away if you:

- get blurred vision or any other changes to your sight
- get persistent coughing or wheezing, shortness of breath, swelling of your ankles and feet, tiredness and increased heart rate.
- get diarrhoea for the first time during treatment with KOSELUGO. Your healthcare provider may give you medicine to help control your diarrhoea and may tell you to drink more fluids.

- get a rash that covers a large area of your body, blisters or peeling skin
- get muscle aches or pain, muscle spasms and weakness or dark, reddish urine
- become pregnant while taking this medicine

Remind any doctor, dentist or pharmacist or other healthcare professional you visit that you are using KOSELUGO.

Things you should not do

- do not stop using this medicine or change the dose without checking with your doctor.
- do not give this medicine to anyone else, even if they have the same condition as you.
- do not use this medicine to treat any other complaints unless your doctor tells you to.
- do not give this medicine to a child younger than 2 years of age.
- do not chew, dissolve, or open the capsules
- Do not become pregnant while taking this medicine

Driving or using machines

KOSELUGO can cause side effects that may affect your ability to drive or use machines. Avoid driving or using machines if you feel tired or if you have problems with your vision (such as blurred vision).

Food and drink

It is important to take KOSELUGO on an empty stomach because food affects the way the medicine is absorbed into your body (see Section 3).

You should not drink grapefruit juice while you are taking KOSELUGO.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store KOSELUGO it in a cool dry place where the temperature stays below 30°C.

Store in the original bottle to protect from moisture. Do not remove the desiccant pack.

Do not use KOSELUGO after the expiry date, which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Do not throw away any medicines via wastewater.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● Stomach related<ul style="list-style-type: none">○ Vomiting○ Stomach pain○ Nausea○ Constipation● Mouth related<ul style="list-style-type: none">○ Inflammation of the mouth● Head and hair related<ul style="list-style-type: none">○ Headache○ Hair thinning (alopecia), hair colour change○ Nosebleeds● Skin and nails related<ul style="list-style-type: none">○ Rash	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ○ Dry skin ○ Redness around the fingernails ● General <ul style="list-style-type: none"> ○ feeling of tiredness, weakness or lacking energy ○ muscle and bone pain ○ fever ○ itching ○ Swelling of the face, hands or feet ○ Decreased appetite 	
<ul style="list-style-type: none"> ● General <ul style="list-style-type: none"> ○ Blood in the urine 	<p>Speak to your doctor as soon as possible if you have this side effect.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● Eye (vision) related <ul style="list-style-type: none"> ○ blurred vision ○ loss of vision ○ dark spots in your vision (floaters) 	<p>Call your doctor straight away, if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ○ other changes to your vision ● Heart related <ul style="list-style-type: none"> ○ persistent coughing and wheezing ○ shortness of breath ○ swelling of your ankles and feet ○ tiredness ○ increased heart rate ● Stomach related <ul style="list-style-type: none"> ○ diarrhoea ● Muscle related <ul style="list-style-type: none"> ○ Muscle aches or pains, muscle spasms and weakness or dark, reddish urine ● Skin related <ul style="list-style-type: none"> ○ Rash that covers a large area of your body, blisters and peeling 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What KOSELUGO 10 mg contains

Active ingredient (main ingredient)	Selumetinib (as sulfate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Tocofersolan• Hypromellose• Carrageenan• Potassium chloride• Titanium dioxide• Carnauba wax• Purified water• Shellac

	<ul style="list-style-type: none"> • Iron oxide black • Propylene glycol • Strong ammonia solution
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What KOSELUGO 25 mg contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> • Selumetinib (as sulfate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Tocofersolan • Hypromellose • Carrageenan • Potassium chloride • Titanium dioxide • Indigo carmine • Iron oxide yellow • Purified water • Carnauba wax • Maize starch • Iron oxide red • Iron oxide yellow • Indigo carmine aluminium lake • Carnauba wax • Shellac • Glyceryl monooleate

Do not take this medicine if you are allergic to any of these ingredients.

What KOSELUGO looks like

KOSELUGO 10 mg hard capsule are white to off-white, opaque capsules, banded and marked with “SEL 10” in black ink. (Aust R 345973).

KOSELUGO 25 mg hard capsule are blue, opaque hard capsules, banded and marked with “SEL 25” in black ink (Aust R 345972).

Who distributes KOSELUGO

Alexion Pharmaceuticals Australasia Pty Ltd

66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone: - 1800 788 189

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