PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

KOSELUGO 10 mg: 10 mg hard capsules

KOSELUGO 25 mg: 25 mg hard capsules

selumetinib

Sugar free

Read all of this leaflet carefully before you start taking KOSELUGO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

- KOSELUGO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What KOSELUGO is and what it is used for
2. What you need to know before you take KOSELUGO
3. How to take KOSELUGO
4. Possible side effects
5. How to store KOSELUGO
6. Contents of the pack and other information

1. What KOSELUGO is and what it is used for

What KOSELUGO is and how it works

KOSELUGO contains the active substance selumetinib.

Selumetinib is a type of medicine called a MEK inhibitor. It works by blocking certain proteins involved in the growth of tumour cells.

KOSELUGO is expected to shrink tumours that grow along nerves, called plexiform neurofibromas. These tumours are caused by a genetic condition called neurofibromatosis type 1 (NF1).

What KOSELUGO is used for

KOSELUGO is used to treat children aged 3 years and above with plexiform neurofibromas that cannot be completely removed by surgery.

If you have any questions about how KOSELUGO works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take KOSELUGO

Do not take KOSELUGO:

- if you are hypersensitive (allergic) to selumetinib or any of the other ingredients of KOSELUGO (listed in section 6).
- if you have severe liver disease

If you are not sure, talk to your doctor, pharmacist or nurse before taking KOSELUGO.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before and during your treatment with KOSELUGO:

- if you have eye problems
- if you have heart problems
- if you have liver problems
- if you take supplements containing vitamin E

- if you cannot swallow the capsule whole

If any of the above apply to you (or you are not sure) talk to your doctor, pharmacist or nurse before taking this medicine.

Eye problems

KOSELUGO can cause eye problems (see section 4 ‘Possible side effects’). **Tell your doctor straight away** 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 this medicine.

Heart problems

KOSELUGO can lower the amount of blood pumped by your heart (see section 4 ‘Possible side-effects’). Your doctor will check how well your heart works before and during your treatment with KOSELUGO.

Liver problems

KOSELUGO can increase the amount of some liver enzymes in your blood (see section 4 ‘Possible side effects’). Your doctor will do blood tests before and during treatment to check how well your liver is working.

Supplemental vitamin E

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

- acetylsalicylic acid (also known as aspirin) for pain and inflammation
- anticoagulant medicines (blood thinners) such as warfarin or other medicines used for preventing blood clots
- supplements that may increase your risk of bleeding, such as vitamin E

Difficulty swallowing capsules

Talk to your doctor if you think you might have difficulties swallowing the capsules whole (see section 3 ‘How to take KOSELUGO’).

Skin, nail and hair problems

KOSELUGO can cause skin rash, nail infection or hair thinning or changes in hair colour (see section 4 ‘Possible side effects’). Tell your doctor if any of these symptoms trouble you during treatment.

Children under 3 years old

Do not give KOSELUGO to children below 3 years of age. This is because it has not been studied in this age group.

Other medicines and KOSELUGO

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes herbal medicines, supplements and medicines obtained without a prescription.

KOSELUGO can affect the way some other medicines work. Also, some other medicines can affect the way KOSELUGO works. Tell your doctor if you are taking any of the following medicines:

- clarithromycin or erythromycin (used to treat bacterial infections)
- carbamazepine or phenytoin (used to treat seizures and epilepsy)
- digoxin (used to treat heart failure)
- fexofenadine (used to treat symptoms of allergy)
- fluconazole or itraconazole (used to treat fungal infections)
- ketoconazole (used to treat Cushing’s syndrome or fungal infections)

- furosemide (used to treat fluid retention by increasing the amount of urine you pass)

- methotrexate (used to treat some types of cancer, psoriasis or rheumatoid arthritis)

- omeprazole (used to treat acid reflux or stomach ulcer)

- rifampicin (used to treat tuberculosis (TB) and some other bacterial infections)

- St. John's wort (Hypericum perforatum), a herbal medicine (used to treat mild depression and other conditions)
- ticlopidine (used to prevent blood clots)

Tell your doctor or pharmacist if you are taking or have recently taken any of the above or any other medicines, even those that are not prescribed.

KOSELUGO with food and drink

Do not drink grapefruit juice while you are taking KOSELUGO because, it can affect the way the medicine works.

Pregnancy, breastfeeding and fertility

Pregnancy – information for women

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

KOSELUGO is not recommended during pregnancy. It may cause harm to an unborn baby.

If you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor may ask you to take a pregnancy test before starting treatment.

You should not become pregnant while taking this medicine. If you are able to become pregnant, you must

use effective contraception. See ‘Contraception-information for women and men’ below.

If you become pregnant during treatment, tell your doctor straight away.

Pregnancy – information for men

If your partner becomes pregnant while you are taking this medicine, tell your doctor straight away.

Contraception – information for women and men

If you are sexually active you should use effective contraception while you are taking this medicine 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.

Breastfeeding

Do not breast-feed if you are taking KOSELUGO. It is not known if KOSELUGO passes into breast milk.

Driving and using machines

KOSELUGO can cause side effects that affect your ability to drive or use machines. Do not drive or use machines if you feel tired or if you have problems with your vision (such as blurred vision).

3. How to take KOSELUGO

Do not share medicines prescribed for you with any other person.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

Your doctor will work out the correct dose for you based on your height and weight. The doctor will tell you how many capsules of KOSELUGO to take.

Your doctor may prescribe a lower dose if you have problems with your liver (hepatic impairment).

Your doctor may reduce your dose if you have certain side effects while you are taking KOSELUGO (see section 4 ‘Possible side effects’) or the doctor may interrupt treatment or stop it permanently.

How to take

- Take KOSELUGO twice a day, about 12 hours apart, with or without food.
- Swallow the 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 are sick (vomit) at any time after taking KOSELUGO, do not take an extra dose. Take the next dose at the normal time.

If you take more KOSELUGO than you should

If you have taken more KOSELUGO than you should, contact your doctor or pharmacist immediately.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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. 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 a forgotten dose.

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, pharmacist or nurse.

4. Possible side effects

KOSELUGO can have side effects.

Not all side effects reported for KOSELUGO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking KOSELUGO, please consult your health care provider for advice.

Possible serious side effects

<u>Eye (vision) problems</u>

KOSELUGO can cause eye problems. Tell your doctor straight away if you get blurred vision (a very common side effect that may affect more than 1 in 10 people) or any other changes to your sight during treatment. Your doctor may ask you to stop taking this medicine or send you to a specialist, if you develop symptoms that include:

- blurred vision
- loss of vision
- dark spots in your vision (floaters)
- other changes to your vision (such as reduced vision)

Tell your doctor straight away if you notice any of the serious side effects above.

Other side effects

Tell your doctor or pharmacist if you notice any of the following side effects:

Very frequent side effects (may affect more than 1 in 10 people):

- being sick (vomiting), feeling sick (nausea)
- diarrhoea
- inflammation of the mouth (stomatitis)
- skin and nail problems - signs may include dry skin, rash, redness around the fingernails

- hair thinning (alopecia), hair colour change
- feeling tired, weak or lacking energy
- fever (pyrexia)
- swelling of the hands or feet (peripheral oedema)
- a slight decrease in the amount of blood that the heart is pumping (ejection fraction decreased) – signs may include shortness of breath or swelling in your legs, ankles or feet

- high blood pressure (hypertension)
- reduced level of albumin, an essential protein in the blood (shown in blood tests)

- reduced haemoglobin, the oxygen - carrying protein in red blood cells (shown in blood tests)

- Increase in enzymes (shown in blood tests) suggesting stress on the liver, kidney injury or muscle breakdown

Frequent side effects (may affect up to 1 in 10 people):

- dry mouth
- swelling of the face (facial oedema)
- shortness of breath (dyspnoea)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of KOSELUGO.

5. How to store KOSELUGO

Store all medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

Store at or below 30 °C

Store in the original bottle in order to protect from moisture and light.

Keep the bottle tightly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw

away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What KOSELUGO contains

The active substance is selumetinib. Each KOSELUGO 10 mg hard capsule contains 10 mg of selumetinib (as hydrogen sulphate). Each KOSELUGO 25 mg hard capsule contains 25 mg of selumetinib (as hydrogen sulphate).

The other ingredients in KOSELUGO 10 mg hard capsules are:

- capsule fill: vitamin E polyethylene glycol succinate (D α-tocopheryl polyethylene glycol succinate).

- capsule shell: hypromellose (E464), carrageenan (E407), potassium chloride (E508), titanium dioxide (E171), carnauba wax (E903).
- printing ink: shellac standard (E904), iron oxide black (E172), propylene glycol (E1520), ammonium hydroxide (E527).

The other ingredients in KOSELUGO 25 mg hard capsules are:

- capsule fill: vitamin E polyethylene glycol succinate (D α-tocopheryl polyethylene glycol succinate).

- capsule shell: hypromellose (E464), carrageenan (E407), potassium chloride (E508), titanium dioxide (E171), indigo carmine aluminium lake (E132), iron oxide yellow (E172), carnauba wax (E903), maize starch.
- printing ink: iron oxide red (E172), iron oxide yellow (E172), indigo carmine aluminium lake (E132), carnauba wax (E903), shellac, standard (E904), glyceryl mono-oleate.

What KOSELUGO looks like and contents of the pack

KOSELUGO 10 mg hard capsule is a white to off-white, opaque, hard capsule which has a centre band and is marked with “SEL10” in black ink.

KOSELUGO 25 mg hard capsule is a blue, opaque, hard capsule which has a centre band and is marked with “SEL25” in black ink.

KOSELUGO is provided in white plastic bottles, capped with a white (10 mg) or blue (25 mg) child-resistant closure containing 60 hard capsules and a silica gel desiccant. Do not remove the desiccant from the bottle and do not swallow it.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

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