KOSELUGO® HARD CAPSULES

Selumetinib (10 mg & 25 mg)

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What Koselugo is used for

Koselugo is used to treat adults and 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.

How Koselugo 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).

Before you use Koselugo

When you must not use it

Do not take Koselugo:
• if you are allergic to selumetinib or any of the other ingredients of this medicine
• if you have severe liver disease

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

Before you start to use it

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 '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 '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 '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 'How to use Koselugo').

Skin, nail and hair problems

Koselugo can cause skin rash, nail infection or hair thinning or changes in hair colour (see 'Side effects'). Tell your doctor if any of these symptoms trouble you during treatment.

Children under 3 years old

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

Taking other 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)

• 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.

How to use Koselugo
How much to use
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 'Side effects') or the doctor may interrupt treatment or stop it permanently.

When to use it
• 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.

How long to use it
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.

If you forget to use it
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 use too much (overdose)
If you have taken more Koselugo than you should, contact your doctor or pharmacist immediately.

While you are using it
Things you must do
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Things you must not do
Do not drink grapefruit juice while you are taking Koselugo because, it can affect the way the medicine works.

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.

Things to be careful of
Pregnancy – information for women
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.

Breast-feeding
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).

Side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible serious side effects
Eye (vision) problems

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
The following side effects have been reported in clinical studies with children receiving Koselugo, tell your doctor or pharmacist if you notice any of the following side effects:

Very common (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

Common (may affect up to 1 in 10 people)
• dry mouth
• swelling of the face (facial oedema)
• shortness of breath (dyspnoea)

The following side effects have been reported in clinical study with adult patients receiving Koselugo, tell your doctor or pharmacist if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people)
• being sick (vomiting), feeling sick (nausea)
• diarrhoea
inflammation of the mouth (stomatitis)
• constipation
• skin and nail problems - signs may include dry skin, rash, redness around the fingernails, rash resembling acne, and inflammation of hair follicles in the skin
• hair thinning (alopecia), hair colour change
• feeling tired, weak or lacking energy
• swelling of the hands or feet (peripheral oedema)
• 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 or kidney injury

Common (may affect up to 1 in 10 people)
• dry mouth
• fever (pyrexia)
• swelling of the face (facial oedema)
• shortness of breath (dyspnoea)
• reduced level of albumin, an essential protein in the blood (shown in blood tests)
• 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)
• increase in enzymes (shown in blood tests) suggesting muscle breakdown

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Koselugo
Storage
Keep this medicine out of the sight and 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.

Do not store above 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.

Disposal
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.

Product Description
What it looks like
Koselugo 10 mg hard capsule is a white to off-white, opaque, size 4

(approximately 14 mm x 5 mm), hard capsule which has a centre band and is marked with “SEL 10” in black ink.

Koselugo 25 mg hard capsule is a blue, opaque, size 4 (approximately 14 mm x 5 mm), hard capsule which has a centre band and is marked with “SEL 25” 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.

Ingredients
Active ingredient:
The active substance is selumetinib. Each Koselugo 10 mg hard capsule contains 10 mg of selumetinib (as hydrogen sulfate). Each Koselugo 25 mg hard capsule contains 25 mg of selumetinib (as hydrogen sulfate).

Inactive ingredients:
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.

MAL number:
Koselugo Hard Capsules 10mg (MAL23046003ACRZ)
Koselugo Hard Capsules 25mg (MAL23046004ACRZ)

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Patheon Pharmaceuticals Inc.,
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