

Package leaflet: Information for the patient

Koselugo® 5 mg granules in capsule for opening **Koselugo® 7.5 mg granules in capsule for opening** selumetinib

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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 granules are used to treat patients with plexiform neurofibromas that cannot be completely removed by surgery for children aged 1 to less than 7 years, and for older patients who have difficulty in swallowing.

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 **allergic to selumetinib** or any of the other ingredients of this medicine (listed in section 6)
- if you have **severe liver disease**

Talk to your doctor, pharmacist or nurse without taking Koselugo, if any of this applies to you.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before and during your treatment with Koselugo, if you have any of the following three conditions listed below:

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.

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

Skin, nail and hair problems

Koselugo can cause skin rash, nail infection, 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 1 year old

Do not give Koselugo granules to children below 1 year of age. This is because it has not been studied in this age group.

Other medicines and Koselugo

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.

Koselugo granules with food and drink

Koselugo granules are given with food but some foods affect the way this medicine works. **Do not give Koselugo granules** in water, milk, vegetable puree, or any juice, fruit puree or jam containing grapefruit or Seville orange (bitter orange), because they can affect this medicine.

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

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).

3. How to take Koselugo

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 the granules

Koselugo granules are sprinkled on, or mixed with soft food. The granules come in a special capsule that can be pulled open. **These capsules are not to be swallowed.** Step-by-step instructions and relevant images for administering the granules can be found in this document.

- Open the capsules carefully.

- **Sprinkle all the granules** inside onto a small amount (approximately 1 to 3 teaspoons) of soft food (for example, smooth yogurt, fruit sauce, fruit puree or fruit jam). Or you can mix the Koselugo granules and soft food together.
- **Do not use** the granules with water, milk, vegetable puree, or with any juice, fruit puree or jam containing **grapefruit or Seville orange** (bitter orange). They can all affect the way this medicine works.
- Once the granules have been sprinkled or mixed, they **must be swallowed within 30 minutes**. They must not be stored for later use.
- Take Koselugo granules **twice a day, about 12 hours apart**.
- The capsule shells of Koselugo granules must not be swallowed, chewed, or dissolved. The empty capsule shells must be discarded after use.

Koselugo is also available as hard capsules, in higher strengths. Children from 3 years age who can swallow capsules may be prescribed Koselugo hard capsules.

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.

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.

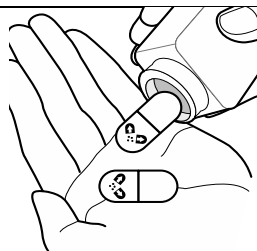
If you stop taking Koselugo

Do not stop taking Koselugo unless your doctor tells you.

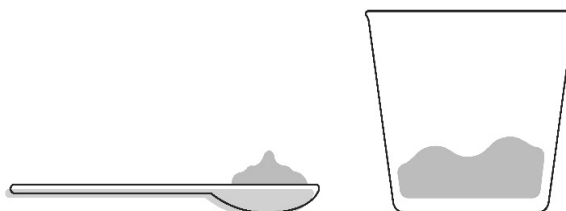
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Preparing to take or give Koselugo granules in capsule for opening

Step 1: Wash and dry your hands thoroughly. Open the bottle and take out the correct number of the correct colour capsule(s) that you will need for the prescribed dose of Koselugo granules in capsule for opening.



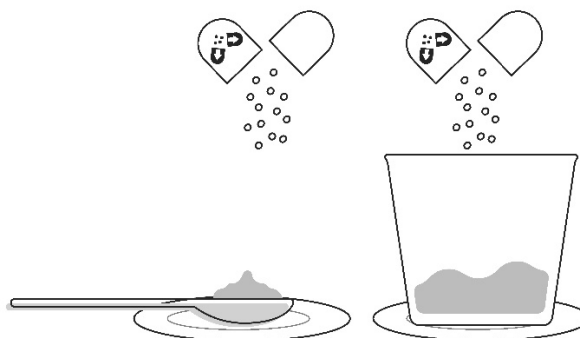
Step 2: Add a small amount (approximately 1 to 3 teaspoons) of soft food such as smooth yogurt, fruit sauce, fruit puree or fruit jam, onto a spoon or into a small cup.



Step 3: One at a time carefully open the capsule(s) and sprinkle the entire contents (granules) onto the soft food that was placed into the spoon or small cup. If using a spoon, you may find it easier to only prepare 1 capsule at a time and repeat steps 2 to 5 until the full dose is taken.

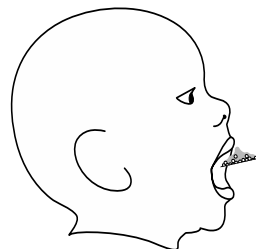
Do not swallow whole capsule(s). **Do not** mix Koselugo granules in water, milk, vegetable puree, or any juice, fruit puree or jam containing grapefruit or Seville orange.

Do not swallow or chew the capsule shells, **do not** chew or crush the granules, and **do not** add granules to liquids.

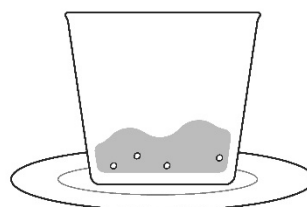


Step 4: Seating in upright position swallow without chewing the Koselugo granules and food mixture within 30 minutes of preparing it. Do not save it for future use.

If Koselugo granules are not taken within 30 minutes, then do not take the dose and prepare a new dose. If a dose has been partially consumed within 30 minutes of preparation, discard remainder of the dose and do not prepare a new dose. Aim to complete dosing within 30 minutes next time.



Step 5: After swallowing the Koselugo granules and food mixture, there may be some leftover in the cup. Add another small amount of chosen food into the cup to take or give the remaining granules. Make sure all the chosen food containing the granules is swallowed.



4. Possible side effects

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

Possible serious side effects

Eye or vision problems

Koselugo can cause eye problems. Tell your doctor straight away if you get blurred vision (a common side effect that may affect up to 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 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, rash resembling acne, and inflammation of hair follicles in the skin
- 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

Reporting of side effects

If you get any side effects, **talk to your doctor, pharmacist or nurse**. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Koselugo

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 25 °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.

Koselugo 5 mg granules in capsule for opening contains 5 mg of selumetinib (as hydrogen sulfate).

Koselugo 7.5 mg granules in capsule for opening contains 7.5 mg of selumetinib (as hydrogen sulfate).

The other ingredients in the 5 mg granules in capsule for opening are:

- granules: glycerol dibehenate, stearyl macrogol glycerides, hypromellose acetate succinate, stearic acid.
- capsule shell: hypromellose (E464), titanium dioxide (E171), yellow iron oxide (E172), printing ink.
- printing ink: shellac (E904), propylene glycol (E1520), concentrated ammonia solution (E527), iron oxide black (E172), potassium hydroxide (E525).

The other ingredients in the 7.5 mg granules in capsule for opening are:

- granules: glycerol dibehenate, stearyl macrogol glycerides, hypromellose acetate succinate, stearic acid.
- capsule shell: hypromellose (E464), titanium dioxide (E171), red iron oxide (E172), printing ink.
- printing ink: shellac (E904), propylene glycol (E1520), concentrated ammonia solution (E527), iron oxide black (E172), potassium hydroxide (E525).

What Koselugo looks like and contents of the pack

Koselugo 5 mg granules in capsule for opening is a hard capsule with a yellow cap and a white body. The cap is printed with 'sel 5' and the body is printed with a sprinkle capsule image indicating opening.

Koselugo 7.5 mg granules in capsule for opening is a hard capsule with a pink cap and a white body. The cap is printed with 'sel 7.5' and the body is printed with a sprinkle capsule image indicating opening.

Koselugo granules in capsule for opening are provided in white plastic bottles, capped with a child-resistant closure containing 60 capsules and a silica gel desiccant. Do not remove the desiccant from the bottle and do not swallow it.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last revised in February 2026.

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine. The Medicines and Healthcare products Regulatory Agency (MHRA) will review new information on this medicine at least every year and this leaflet will be updated as necessary.

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ONC 26 0004

Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Koselugo 5 mg granules in capsule for opening	17901/0387
Koselugo 7.5 mg granules in capsule for opening	17901/0388

This is a service provided by the Royal National Institute of the Blind.