

Package leaflet: Information for the patient

Hyrnuo 10 mg film-coated tablets sevabertinib

▼ 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 Hyrnuo is and what it is used for
2. What you need to know before you take Hyrnuo
3. How to take Hyrnuo
4. Possible side effects
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1. What Hyrnuo is and what it is used for

What Hyrnuo is

Hyrnuo belongs to a group of cancer medicines called protein kinase inhibitors. It contains the active substance sevabertinib.

What Hyrnuo is used for

Hyrnuo is used to treat adults with non-small cell lung cancer (NSCLC).

It is prescribed when the cancer has certain changes (activating mutations) in a gene named '*HER2*' (human epidermal growth factor receptor 2), and

- the cancer has spread to other parts of the body or cannot be removed by surgery and
- the patient has already received another treatment for the cancer.

Before you are given Hyrnuo, a test must have been done to check if your cancer has a change in the *HER2* gene to make sure that Hyrnuo is right for you.

How Hyrnuo works

The *HER2* protein is found on the surface of some cells in the body. It helps control how normal cells grow and divide.

A change in the *HER2* gene can make the body produce an abnormal *HER2* protein. This can cause cells to grow without control and lead to cancer.

Hyrnuo stops the abnormal protein from working and may slow down or stop the growth of the cancer. It may also help to shrink the cancer.

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

2. What you need to know before you take Hyrnuo

Do not take Hyrnuo

- if you are allergic to sevabertinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse immediately while taking Hyrnuo:

- if you develop diarrhoea (having unformed stools). Immediate treatment of diarrhoea is important (see also section 4 'Possible side effects').
- if you develop sudden difficulty in breathing, cough, or fever. Hyrnuo may cause inflammation of the lungs during treatment. Your doctor will monitor you for potential symptoms (see also section 4 'Possible side effects').
- if you develop eye problems. Hyrnuo can cause problems with your eyes that could lead to temporary loss of vision. Your doctor may send you to see an eye specialist (ophthalmologist) if you develop new or worsening eye problems during treatment with Hyrnuo (see also section 4 'Possible side effects').

Monitoring of liver and pancreatic function

Your doctor will carry out blood tests to check how well your liver and pancreas are working.

Children and adolescents

This medicine is not recommended in children or adolescents below 18 years of age because the safety and efficacy of Hyrnuo have not been established in this age group.

Other medicines and Hyrnuo

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained with or without a prescription, or over-the-counter medicines such as vitamins, dietary supplements or herbal medicines.

Some medicines may influence the effect of Hyrnuo, or Hyrnuo may influence the effect of other medicines.

In particular, tell your doctor if you are taking any of the following medicines:

Medicine or active substance	Typically used to treat
clarithromycin, itraconazole, ketoconazole, rifampicin, rifabutin	fungal and bacterial infections
cobicistat, lopinavir/ritonavir, saquinavir/ritonavir	HIV infection/AIDS
carbamazepine, phenytoin	epilepsy (seizures)
St. John's Wort (a herbal medicine)	slightly low mood and mild anxiety
alfentanil, fentanyl	pain relief
cyclosporine, sirolimus, tacrolimus	prevent organ rejection after transplantation
dihydroergotamine, ergotamine	migraine
pimozide	an antipsychotic drug used to control motor or verbal tics

quinidine	abnormal heart rhythms
digoxin	heart problems
methotrexate	severe joint inflammation, severe cases of skin disease psoriasis, cancers
atorvastatin	high cholesterol
riociguat	pulmonary hypertension
granisetron	prevention of nausea and vomiting
metformin	diabetes
cisplatin	certain types of cancer

Ask your doctor, pharmacist or nurse for advice before taking any medicine.

Hyrnuo with food and drink

Do not eat grapefruit or drink grapefruit juice while you are taking Hyrnuo. This is because it may increase your chance of getting side effects by increasing the amount of Hyrnuo in your body.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

- Avoid becoming pregnant while taking Hyrnuo because this medicine could harm the unborn child.
- Your doctor will perform a pregnancy test before you start taking Hyrnuo if you could become pregnant.
- Tell your doctor straight away if you become pregnant while taking this medicine. Your doctor will decide with you whether treatment should be continued or not.

Contraception – female patients

If you **could become pregnant**, you **must use a highly effective method of contraception** to avoid becoming pregnant

- while you are taking Hyrnuo and
- for 1 week after you stop taking it.

Contraception – male patients

If you are **a man with a partner who could become pregnant**, you **must use a highly effective method of contraception** to avoid pregnancy

- while you are taking Hyrnuo and
- for 1 week after you stop taking it.

If you are a man and you have sex with a woman who is pregnant: use a condom while you are taking Hyrnuo and for 1 week after you stop taking it. This is important because the semen fluid containing Hyrnuo may negatively affect the development of the unborn child.

Talk to your doctor about the right methods of contraception for you and your partner.

Breast-feeding

You should not breast-feed during treatment with this medicine and for 1 week after you stop taking it. Hyrnuo could harm your breast-fed child. **Tell your doctor if you are breast-feeding or planning to breast-feed** before taking this medicine.

Driving and using machines

This medicine is unlikely to affect your ability to drive and use machines.

Hyrnuo contains lactose

If you have been told by a doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.

3. How to take Hyrnuo

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

How much Hyrnuo to take

Adults (from 18 years)

The recommended dose is 2 tablets two times a day. This is a total of 4 tablets per day.

Do not take more than the recommended daily dose.

Recommended dose of Hyrnuo

Morning	2 x 10mg tablets
	
	with food
Evening	2 x 10mg tablets
	
	with food

Your doctor may change your dose or may recommend to pause or stop taking Hyrnuo if necessary. Take the dose of Hyrnuo that your doctor prescribes for you.

How to take Hyrnuo

- Take the tablets with food.
- Swallow the tablets whole with a glass of water.
- Do not chew, break or crush the tablets.

If you take more Hyrnuo than you should

If you have taken too much Hyrnuo, or if someone else accidentally takes your medicine, contact a doctor or go to a hospital straight away. Take the medicine pack and this leaflet with you. Medical treatment may be necessary.

If you vomit after taking a dose of Hyrnuo

Do not take an additional dose. Take your next dose at your next scheduled time.

If you forget to take Hyrnuo

Take your missed dose as soon as you remember. However, if it is less than 30 minutes until your next dose, skip the missed dose and take your next dose at the scheduled time. Do not take a double dose at your next scheduled time to make up for a forgotten tablet.

If you stop taking Hyrnuo

Do not stop taking Hyrnuo unless your doctor tells you to. It is important to take Hyrnuo for as long as your doctor prescribes it for you.

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

4. Possible side effects

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

Tell your doctor immediately if you have any of the following side effects. In some cases, your doctor may decide to lower the dose or pause or stop the treatment.

- **Diarrhoea** (having unformed stools; very common: may affect more than 1 in 10 people). Hyrnuo can cause diarrhoea early during treatment. Diarrhoea can cause your body to lose too much water and important minerals. At the first signs of diarrhoea, contact your doctor immediately, drink plenty of fluids and start anti-diarrhoeal treatment as soon as possible. You should have an anti-diarrhoeal medicine available before you start taking Hyrnuo.
Inflammation of the lungs (interstitial lung disease/pneumonitis; uncommon, may affect up to 1 in 100 people). Tell your doctor immediately if you experience sudden difficulty in breathing, cough, or fever that may suggest inflammation of the lungs.
- **Eye problems** (ocular toxicity; common may affect up to 1 in 10 people). Tell your doctor immediately if you experience eye problems like dry eyes, blurred vision, blind spots on the eye.
- **Changes in blood tests for liver function** (higher levels of alanine aminotransferase, aspartate aminotransferase, bilirubin, and alkaline phosphatase; very common, may affect more than 1 in 10 people). Tell your doctor immediately if you experience a combination of yellowing of the skin or white part of your eyes (jaundice), dark urine, pale stools, tiredness or weakness, nausea or vomiting, loss of appetite and pain on the upper right side of your stomach.
- **Changes in blood tests for pancreatic function** (higher levels of amylase and lipase which are certain enzymes involved in digestion; very common, may affect more than 1 in 10 people). Tell your doctor immediately if you experience upper stomach pain that may spread to your back and get worse with eating, weight loss, nausea or vomiting.

Tell your doctor if you notice any of the following **other side effects** listed below by how common they are with Hyrnuo.

Very common: may affect more than 1 in 10 people

- redness, irritation, or bumps on the skin (rash)
- mouth sores, inflammation, or ulcer (stomatitis)
- nail problems including ingrowing nails, nails separating from the nail bed, nail infection, nail splitting or colour change (paronychia)
- low levels of potassium in the blood (hypokalaemia)
- nausea with or without vomiting
- dry skin
- loss of appetite (decreased appetite)
- itching (pruritus)
- low number of red blood cells which makes you feel tired, look pale and you may feel your heart pumping (anaemia)

- weight loss (decreased weight)

Common: may affect up to 1 in 10 people

- feeling tired, or lacking energy (fatigue)
- feeling pain or discomfort in the stomach or belly area (abdominal pain)
- hair loss (alopecia)
- pain, redness, swelling or peeling of the skin of your hands and feet (palmar-plantar erythrodysesthesia syndrome)
- abnormal or irregular heartbeat (cardiac arrhythmia)

Side effects that may show up in your blood tests:

Very common: may affect more than 1 in 10 people

- blood tests showing a lower number of white blood cells (including lymphocytes) which may decrease your ability to fight infection
- changes in blood tests for kidney function (higher levels of creatinine)
- changes in blood tests for minerals (lower levels of potassium, magnesium, calcium and sodium)
- changes in blood sugar tests (higher levels of sugar in the blood)
- changes in blood fat tests (higher levels of blood triglycerides, a type of fat)
- blood tests showing lower levels of albumin

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: 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 Hyrnuo

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 carton and on each blister pack after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Hyrnuo contains

- The active substance is sevabertinib. Each film-coated tablet contains 10 mg of sevabertinib
- The other ingredient(s) are:
 - Tablet core: cellulose microcrystalline, crospovidone (E 1202), lactose monohydrate, magnesium stearate (E 470b).
 - Film coat: ferric oxide red (E 172), hypromellose 5 cP (E 464), macrogol 3350 (E 1521).

What Hyrnuo looks like and contents of the pack

Hyrnuo 10 mg film-coated tablets are red brown, round and biconvex, approximately 6 mm diameter. They are debossed with “SE” on one side and “10” on the other side.

Hyrnuo is available in cartons with foil blisters containing:

- 112 (28x4) film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Bayer plc
400 South Oak Way
Reading
RG2 6AD

Manufacturer

Bayer AG
Kaiser-Wilhelm-Allee
51368 Leverkusen
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For any information about this medicine, please contact the Marketing Authorisation Holder:

Bayer plc
Tel: 0118 206 3000

This leaflet was last revised in 03/2026.

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.

The MHRA will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Other sources of information

For information in large print, CD or Braille, phone 0118 206 3116, or email medical.information@bayer.co.uk, quoting PL 00010/0764.