

PATIENT INFORMATION
HYRNUO® (Her noo' oh)
(sevabertinib)
tablets, for oral use

What is HYRNUO?

HYRNUO is a prescription medicine that is used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC) that:

- has spread within your chest or to other parts of the body, **and**
- has a certain abnormal human epidermal growth factor receptor 2 (*HER2*) gene(s), **and**
- who have received a previous treatment (systemic therapy).

Your healthcare provider will perform a test to make sure HYRNUO is right for you.

It is not known if HYRNUO is safe and effective in children.

Before taking HYRNUO, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems.
- have lung or breathing problems other than lung cancer.
- are pregnant or plan to become pregnant. HYRNUO can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with HYRNUO.
- Use effective birth control (contraception) during treatment and for 1 week after the last dose of HYRNUO.
- Talk to your healthcare provider about birth control methods that may be right for you.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during your treatment with HYRNUO.

Males with female partners who are able to become pregnant:

- Use effective birth control (contraception) during treatment and for 1 week after your last dose of HYRNUO.
- Talk to your healthcare provider about birth control methods that may be right for you and your partner.
- are breastfeeding or plan to breastfeed. It is not known if HYRNUO passes into breast milk. Do not breastfeed during treatment and for 1 week after the last dose of HYRNUO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. HYRNUO may affect the way other medicines work, and other medicines may affect how HYRNUO works.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take HYRNUO?

- Take HYRNUO exactly as your healthcare provider tells you.
- Do not change your dose or stop taking HYRNUO unless your healthcare provider tells you to.
- Take HYRNUO 2 times a day with food.
- Swallow HYRNUO tablets whole with a glass of water.
- Do not cut, crush or chew HYRNUO tablets.
- If you miss a dose of HYRNUO, take your prescribed dose as soon as you remember before the next scheduled dose. Do not take 2 doses at the same time to make up for a missed dose.
- If you vomit after taking a dose of HYRNUO, do not make up the dose. Take your next dose at your regularly scheduled time.

What should I avoid while taking HYRNUO?

- Avoid eating grapefruit or drinking grapefruit juice during treatment with HYRNUO. Grapefruit may increase the amount of HYRNUO in your blood.

What are the possible side effects of HYRNUO?

HYRNUO may cause serious side effects, including:

- **diarrhea.** Diarrhea is common and can be severe during treatment with HYRNUO and usually occurs in the first week of treatment. Diarrhea can cause the loss of body fluids (dehydration) and salts (electrolyte imbalances). At the first signs of diarrhea (loose stool) or increased bowel movements, tell your healthcare provider right away, drink plenty of fluids and start treatment for diarrhea as soon as possible. You should have an anti-diarrhea medicine available before you start taking HYRNUO.
- **liver problems.** HYRNUO can cause increases in liver blood tests which may be severe. Your healthcare provider will do blood tests to check your liver function before you start taking and during treatment with HYRNUO. Tell your healthcare provider right away if you develop any signs and symptoms of liver problems including:
 - yellowing of the skin or white part of your eyes (jaundice)
 - dark urine
 - pale stools
 - tiredness or weakness
 - nausea or vomiting
 - loss of appetite
 - pain on the upper right side of your stomach

- **lung problems.** HYRNUO may cause severe lung problems. Tell your healthcare provider right away if you develop any new or worsening symptoms of lung problems during treatment with HYRNUO, including:
 - cough
 - fever
 - shortness of breath or trouble breathing
- **eye problems.** HYRNUO can cause eye problems that can lead to temporary loss of vision. Your healthcare provider may send you to see an eye specialist (ophthalmologist) if you develop new or worsening eye problems during treatment with HYRNUO.
- **pancreas problems.** HYRNUO may cause increases in certain pancreatic lab tests (amylase and lipase). Your healthcare provider will do blood tests to check your pancreatic function before and during treatment with HYRNUO. Tell your healthcare provider right away if you develop any signs and symptoms of pancreas problems, including:
 - upper stomach pain that may spread to your back and get worse with eating
 - weight loss
 - nausea or vomiting

Your healthcare provider may change your dose, temporarily stop, or completely stop your treatment with HYRNUO if you have certain side effects.

The most common side effects of HYRNUO include:

- rash
- nail problems including infection and inflammation
- mouth sores
- nausea
- changes in certain blood tests

These are not all of the possible side effects of HYRNUO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store HYRNUO?

- Store HYRNUO at room temperature between 68°F to 77°F (20°C to 25°C).
- HYRNUO comes in a child-resistant container.

Keep HYRNUO and all medicines out of the reach of children.

General information about the safe and effective use of HYRNUO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use HYRNUO for a condition for which it was not prescribed. Do not give HYRNUO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about HYRNUO that is written for health professionals.

What are the ingredients in HYRNUO?

Active ingredient: sevabertinib

Inactive ingredients: cellulose microcrystalline, crospovidone, lactose monohydrate, and magnesium stearate.

Tablet film coating: ferric oxide red, hypromellose 5 cP, and macrogol 3350.

Manufactured for: Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ 07981 USA

For more information, call Bayer HealthCare Pharmaceuticals Inc. at Bayer at 1-888-842-2937 or go to www.HYRNUO-us.com

This Patient Information has been approved by the U.S. Food and Drug Administration.

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