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

What is HYRNUO?

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

- has spread within the chest (locally advanced) or to other parts of the body (metastatic), **and**
- has a certain abnormal human epidermal growth factor receptor 2 (*HER2*) gene(s).

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.
- have heart problems.
- have vision or eye problems.
- 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.
- **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.

What are the possible side effects of HYRNUO?

HYRNUO may cause serious side effects, including:

- **diarrhea**. Diarrhea 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 treatment with HYRNUO.
- **liver problems.** HYRNUO may cause severe liver problems, including increases in liver blood tests. Your healthcare provider will do blood tests to check your liver function before you start 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
  - nausea or vomiting
  - loss of appetite
  - pain on the upper right side of your stomach
  - tiredness or weakness

- **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
- **heart problems.** HYRNUO may cause severe heart problems that may affect your heart's ability to pump blood. Your healthcare provider will do tests to check your heart function before you start and during treatment with HYRNUO. Tell your healthcare provider right away if you develop any new or worsening signs or symptoms of heart problems, including:
  - shortness of breath
  - tiredness
  - coughing
  - irregular heartbeat
  - swelling of your legs, ankles, or feet
  - feeling dizzy or lightheaded
  - loss of consciousness
- **eye problems**. HYRNUO can cause eye problems that can lead to temporary loss of vision. Tell your healthcare provider right away if you develop new or worsening signs or symptoms of eye problems. Your healthcare provider may send you to an eye specialist (ophthalmologist).
- **pancreas problems**. HYRNUO may cause increases in certain pancreatic blood tests (amylase and lipase). Your healthcare provider will do blood tests to check your pancreatic function 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:

- diarrhea
- rash
- nail problems including infection and inflammation
- mouth sores
- nausea
- vomiting
- 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 pharmacist or healthcare provider 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 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. Revised: 09/2026