

Patient Information
IDVYNSO™ (ihd-VIHN-soh)
(doravirine and islatravir)
tablets

What is IDVYNSO?

IDVYNSO is a prescription medicine that is used without other Human Immunodeficiency Virus-1 (HIV-1) medicines to treat HIV-1 infection in adults to replace their current HIV-1 medicines for people whose healthcare provider determines that they meet certain requirements.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

IDVYNSO contains the prescription medicines doravirine and islatravir.

It is not known if IDVYNSO is safe and effective in children under 18 years of age.

Do not take IDVYNSO if you take:

- certain medicines called strong CYP3A inducers which increase the enzyme CYP3A in your liver.
- lamivudine or emtricitabine.

These medicines can make IDVYNSO less effective. Ask your healthcare provider or pharmacist if you are not sure if any of your medicines are strong CYP3A inducers. If you have taken any of the medicines in the past 4 weeks, talk to your healthcare provider or pharmacist before starting treatment with IDVYNSO.

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

- have liver problems
- have ever had hepatitis B virus infection
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if IDVYNSO can harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with IDVYNSO.

Pregnancy Registry: There is a pregnancy registry for people who take IDVYNSO during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. It is not known if IDVYNSO passes into your breast milk. Talk with your healthcare provider about the following risks to your baby from breastfeeding during treatment with IDVYNSO:
 - the HIV-1 virus may pass to your baby if your baby does not have HIV-1.
 - the HIV-1 virus may become harder to treat if your baby has HIV-1.
 - your baby may get side effects from IDVYNSO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

- Some medicines interact with IDVYNSO. Keep a list of your medicines to show your healthcare provider and pharmacist.
- Tell your healthcare provider if you have taken rifabutin in the past 4 weeks.
- You can ask your healthcare provider or pharmacist for a list of medicines that interact with IDVYNSO.
- Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take IDVYNSO with other medicines.

How should I take IDVYNSO?

- Take IDVYNSO every day exactly as your healthcare provider tells you to take it.
- Take IDVYNSO 1 time each day, at about the same time every day.
- Take IDVYNSO with or without food.
- IDVYNSO is taken by itself (without other HIV-1 medicines).
- If you take the medicine rifabutin during treatment with IDVYNSO, your healthcare provider will also prescribe an additional dose of doravirine for you. You may not have enough doravirine in your blood if you take rifabutin during treatment with IDVYNSO. Carefully follow your healthcare provider's instructions about when to take doravirine and how much to take. This is usually 1 tablet of doravirine about 12 hours after your dose of IDVYNSO.
- Do not change your dose or stop taking IDVYNSO without talking to your healthcare provider. Stay under a healthcare provider's care when taking IDVYNSO.

- It is important that you do not miss or skip doses of IDVYNSO.
- If you miss a dose of IDVYNSO, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose, and take the next dose at your regular time. Do not take 2 doses of IDVYNSO at the same time.
- If you have any questions, call your healthcare provider or pharmacist.
- If you take too much IDVYNSO, call your healthcare provider or go to the nearest hospital emergency room right away.
- When your supply of IDVYNSO starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to IDVYNSO and become harder to treat.

What are the possible side effects of IDVYNSO?

IDVYNSO may cause serious side effects including:

- **Severe skin reactions** have happened in people treated with IDVYNSO. Call your healthcare provider right away if you develop a rash during treatment with IDVYNSO. **Stop taking IDVYNSO and get medical help right away if you develop a painful rash with any of the following symptoms:**
 - fever
 - blisters or peeling of the skin
 - feeling tired or generally ill
 - blisters or sores in the mouth
 - swelling of the face or lymph nodes
 - redness or swelling of the eyes (conjunctivitis)

The most common side effects of IDVYNSO include:

- diarrhea
- dizziness
- tiredness
- stomach (abdominal) bloating
- headache
- weight gain

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

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 IDVYNSO?

- Store IDVYNSO tablets at room temperature between 68°F and 77°F (20°C to 25°C).
- Keep IDVYNSO in the original bottle.
- Do not take the tablets out of the bottle to store in another container, such as a pill box.
- Keep the bottle tightly closed to protect IDVYNSO from moisture.
- The IDVYNSO bottle contains desiccants to help keep your medicine dry (protect it from moisture). Keep the desiccants in the bottle. **Do not eat the desiccants.**

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

General information about the safe and effective use of IDVYNSO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use IDVYNSO for a condition for which it was not prescribed. Do not give IDVYNSO 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 IDVYNSO that is written for healthcare professionals.

What are the ingredients in IDVYNSO?

Active ingredients: doravirine and islatravir

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, microcrystalline cellulose.

The tablet film coating contains calcium carbonate, ferric oxide, ferrous ferric oxide, hypromellose, lactose monohydrate, and triacetin. The coated tablets are polished with carnauba wax.

Manufactured for Merck Sharp & Dohme LLC, Rahway, NJ 07065, USA

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

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