rilpivirine (Edurant)

WHAT IS RILPIVIRINE?

Rilpivirine, also known as rilpivirine hydrochloride or RPV (brand name Edurant), is a drug used as part of antiretroviral therapy (ART). The FDA approved rilpivirine in 2011 as an antiretroviral drug (ARV) for people with HIV infection. Rilpivirine is manufactured by Janssen Therapeutics.

Rilpivirine is a type of drug called a non-nucleoside reverse transcriptase inhibitor (NNRTI). NNRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used in combination with other ARVs to treat HIV infection, rilpivirine may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing the CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Rilpivirine does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE RILPIVIRINE?

Rilpivirine is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults and children 12 years of age and older who weigh at least 77 pounds (35 kg) and who:

- have not received HIV medicines in the past
  AND
- have a viral load that is less than or equal to 100,000 copies/mL.

The safety and effectiveness of rilpivirine has not been established in children less than 12 years of age who weigh less than 77 pounds (35 kg). Rilpivirine has not been carefully studied in the elderly (65 years of age and older).

Rilpivirine is also used with oral cabotegravir (Vocabria) for short term treatment of HIV infection in adults when their healthcare provider determines that they meet certain requirements.

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

WHO SHOULD NOT TAKE RILPIVIRINE?

Do not take rilpivirine if you take any of the following medicines:

- Seizure medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicines: rifampin, rifapentine
- Herbal product: John's Wort (Hypericum perforatum)
- Proton pump inhibitor (PPI) medicines for stomach/intestinal problems: esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole
- Steroid medicine: dexamethasone (more than a single dose)

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with rilpivirine.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING RILPIVIRINE?

Before you take rilpivirine, tell your healthcare provider about all of your medical conditions, and in particular if you:

- have ever had a severe skin rash or an allergic reaction to medicines that contain rilpivirine

- have or had liver problems, including hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
- have kidney problems
- have ever had a mental health problem

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with rilpivirine. It is not known if rilpivirine will harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with rilpivirine. It is not known if rilpivirine can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS RILPIVIRINE TAKEN?

Rilpivirine is taken by mouth as a tablet or as an injection in combination with cabotegravir. The recommended dosage of rilpivirine for adults and children 12 years of age and older who weigh at least 77 pounds (35 kg) is one 25 mg tablet once daily, in combination with other ARVs.

You should take rilpivirine at the same time each day with meals. A protein drink alone does not replace a meal.

If you take an H2-receptor antagonist (famotidine, cimetidine, nizatidine, or ranitidine), take these medicines at least 12 hours before or at least 4 hours after you take rilpivirine.

If you take antacids, or other products that contain aluminum, calcium carbonate, or magnesium hydroxide, take these medicines at least 2 hours before or at least 4 hours after you take rilpivirine.

You need to take rilpivirine in combination with other ARVs. Your healthcare provider will tell you what medicines to take and how to take them.

Rilpivirine is also available in several combination medications. Combination HIV medicines contain two or more HIV medicines from one or more drug classes.

- cabotegravir/rilpivirine (Cabenuva)
- dolutegravir/rilpivirine (Juluca)
- emtricitabine/rilpivirine/tenofovir DF (Complera)
- rilpivirine/emtricitabine/tenofovir AF (Odefsey)

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of rilpivirine are depression, headaches, trouble sleeping (insomnia), and rash.

Rilpivirine can cause serious side effects including:

Severe skin rash and allergic reactions. Skin rash is a common side effect of rilpivirine. Call your healthcare provider right away if you develop a rash with rilpivirine. In some cases, rash and allergic reaction may need to be treated in a hospital. Stop taking rilpivirine and get medical help if you develop a rash with any of the following signs or symptoms:

- Fever
- Generally feeling ill
- Extreme tiredness
- Muscle or joint aches
- Blisters or sores in mouth
- Blisters or peeling of the skin
- Redness or swelling of the eyes

- Swelling of the mouth, lips, or face
- Problems breathing

Liver problems. People with a history of HBV or HCV infection or who have certain liver function test changes may have an increased risk of developing new or worsening changes in certain liver tests during treatment with rilpivirine. Liver problems have also happened in people without a history of problems or other risk factors. Your healthcare provider may need to do tests to check your liver function before and during treatment with rilpivirine. Call your healthcare provider if you develop any of the following signs or symptoms of liver problems:

- Yellowing of your skin or whites of your eyes
- Dark or "tea colored" urine
- Pale colored stools (bowel movements)
- Nausea or vomiting
- Loss of appetite
- Pain, aching, or tenderness on the right side of your stomach area

Depression or mood changes. Call your healthcare provider if you have any of the following symptoms of depression or mood changes.

- Feeling sad or hopeless
- Feeling anxious or restless
- Have thoughts of hurting yourself (suicide) or have tried to hurt yourself

Changes in body fat. Changes in body fat distribution or accumulation have happened in some people taking HIV medicines, including an increased amount of fat in the upper back and neck (buffalo hump), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these body fat changes are not known.

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting rilpivirine.

These are not all the possible side effects of rilpivirine. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES RILPIVIRINE REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take rilpivirine with other medicines.

See above for a list of medicines that you should not take with rilpivirine.

MORE INFORMATION

Visit the Edurant website

Visit the Edurant healthcare professional website

Download the full Prescribing Information

Visit the Janssen CarePath website for Edurant

If you take rilpivirine in combination with oral cabotegravir (Vocabria), you should also read the Patient Information that comes with oral cabotegravir (Vocabria)

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