Cabenuva

WHAT IS CABENUVA?

Cabenuva is a long-acting, complete HIV regimen used as part of antiretroviral therapy (ART). Cabenuva combines two antiretroviral drugs (ARVs):

- cabotegravir extended-release injectable suspension
- rilpivirine extended-release injectable suspension

The FDA approved Cabenuva in 2021 as an ARV for people with HIV infection. Cabenuva is manufactured by ViiV Healthcare.

One of the drugs in Cabenuva, cabotegravir, is a type of drug called an integrase inhibitor. Integrase inhibitors block integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of host CD4 cells. Blocking integrase prevents HIV from replicating. The other drug in Cabenuva, rilpivirine, is 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 alone as a complete regimen to treat HIV infection, Cabenuva 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 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.

Cabenuva 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 CABENUVA?

Cabenuva is a prescription combination medication used alone as a complete regimen to treat HIV infection in adults to replace their current HIV medicines when their healthcare provider determines that they meet certain requirements.

The safety and effectiveness of Cabenuva has not been established in children under 18 years of age. Cabenuva has not been carefully studied in the elderly (65 years of age and older).

All people living 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.

Cabenuva provides 2 drugs in one monthly injection and is designed to keep you undetectable for an entire month. While you're getting your regular monthly injections, you won't have to take any other drugs to treat your HIV. **Cabenuva is used as a complete regimen for the treatment of HIV infection.**

WHO SHOULD NOT TAKE CABENUVA?

Do not take Cabenuva if you are allergic to cabotegravir, rilpivirine, or any of the ingredients in this drug.

Do not take Cabenuva if you are taking any of the following medicines. Taking Cabenuva with these medicines may affect how Cabenuva works. Cabenuva may cause serious or life-threatening side effects or death when used with these medicines:

- Seizure medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicines: rifabutin, rifampin, rifapentine
- Herbal product: St. John's Wort (*Hypericum perforatum*)
- Steroid medicine: dexamethasone (more than a single-dose treatment)

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 Cabenuva.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING CABENUVA?

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

- Have ever had a skin rash or an allergic reaction to medicines that contain cabotegravir or rilpivirine
- Have or have had liver problems, including hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
- Have ever had mental health problems

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 Cabenuva. It is not known if Cabenuva can harm your unborn baby. Cabenuva can remain in your body for up to 12 months or longer after the last injection.

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 Cabenuva. It is not known if Cabenuva can pass to your baby in your breastmilk. Do 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 CABENUVA GIVEN?

Cabenuva is administered by a healthcare professional once a month. You will receive Cabenuva as two injections (cabotegravir and rilpivirine) into the muscle of each side of your buttocks one time every month.

Before receiving your first injection doses of Cabenuva, your healthcare provider will have you take cabotegravir and rilpivirine by mouth daily for one month (at least 28 days) to assess how well you tolerate these medicines. The recommended oral lead-in daily dose is one 30-mg tablet of cabotegravir (Vocabria) and one 25-mg tablet of rilpivirine (Edurant).

Cabenuva is a long-acting medicine and may stay in your system for 12 months or longer after your last injection. Stay under the care of a healthcare provider during treatment with Cabenuva. It is important that you attend your planned appointments to receive your injection doses of Cabenuva. If you miss or plan to miss a scheduled monthly injection of Cabenuva by more than 7 days, call your healthcare provider right away to discuss your treatment options.

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 Cabenuva include

- Pain, tenderness, hardened mass or lump, swelling, redness, itching, bruising, and warmth at the injection site
- Fever
- Tiredness
- Headaches
- Muscle or bone pain
- Nausea
- Sleep problems
- Dizziness
- Rash
- Depression

Cabenuva can cause serious side effects including:

Allergic reactions. Call your healthcare provider right away if you develop a rash with Cabenuva. Stop receiving Cabenuva and get medical help right away if you develop a rash with any of the following signs or symptoms:

- Fever
- Generally ill feeling
- Tiredness
- Muscle or joint aches

- Trouble breathing
- Blisters or sores in mouth
- Blisters
- Redness or swelling of the eyes
- Swelling of the mouth, face, lips, or tongue

Post-injection reactions. Post-injection reaction symptoms have happened within minutes in some people after receiving their rilpivirine injection. Most symptoms resolved within a few minutes after the injection. Symptoms of post-injection reactions may include:

- Trouble breathing
- Stomach cramps
- Sweating
- Numbness of your mouth
- Feeling anxious
- Feeling warm
- Feeling lightheaded or feeling like you are going to pass out (faint)
- Blood pressure changes

Liver problems. People with a history of HBV or HCV or people 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 Cabenuva. Liver problems have also happened in people without history of liver problems or other risk factors. Your healthcare provider may do blood tests to check your liver function. Call your healthcare provider right away if you develop any of the following signs or symptoms of liver problems:

- Your skin or the white part of your eyes turns yellow
- Dark or “tea-colored” urine
- Light-colored stools (bowel movements)
- Nausea or vomiting
- Loss of appetite for several days or longer
- Pain or tenderness on the right side of your stomach area
- Itching

Depression or mood changes. Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms:

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

These are not all the possible side effects of Cabenuva. 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 CABENUVA 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 Cabenuva with other medicines.

See above for a list of medicines that should not be taken with Cabenuva.

Cabenuva is a complete regimen for the treatment of HIV infection; therefore, taking Cabenuva with other ARVs for the treatment of HIV infection is not recommended.

MORE INFORMATION

Visit the Cabenuva website.

Visit the Cabenuva healthcare professional website.

Download the full Prescribing Information.

Download the Patient Information leaflet.

Check out the ViiV Healthcare Patient Assistance Program.

Get a ViiV Healthcare Savings Card.

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