

Important Facts About CABENUVA

This is only a brief summary of important information about CABENUVA and does not replace talking to your healthcare provider about your condition and treatment.

(kab' en ue vah)

ABOUT CABENUVA

CABENUVA is a complete prescription regimen used to treat HIV-1 infection in adults as a replacement for their current HIV-1 treatment when their healthcare provider determines that they meet certain requirements.

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

CABENUVA contains 2 different medicines:

- cabotegravir
- rilpivirine

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

DO NOT RECEIVE CABENUVA IF YOU

- have ever had an allergic reaction to cabotegravir or rilpivirine.
- are taking certain medicines:
 - carbamazepine
 - oxcarbazepine
 - phenobarbital
 - phenytoin
 - rifabutin
 - rifampin
 - rifapentine
 - dexamethasone (more than a single-dose treatment), and/or
 - St John's wort (*Hypericum perforatum*)

BEFORE RECEIVING CABENUVA

Tell your healthcare provider about all your medical conditions, including 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 or C infection.
- have ever had mental health problems.
- are pregnant or plan to become pregnant. It is not known if CABENUVA will harm your unborn baby. CABENUVA can remain in your body for up to 12 months or longer after the last injection.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take CABENUVA.**
 - You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. It is not known if CABENUVA can pass to your baby in your breast milk.
 - Talk with your healthcare provider about the best way to feed your baby during treatment with CABENUVA.

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 CABENUVA. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine. You can ask your healthcare provider or pharmacist for a list of medicines that interact with CABENUVA.

Do not start taking a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take CABENUVA with other medicines.

POSSIBLE SIDE EFFECTS OF CABENUVA

CABENUVA may 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** have happened within minutes in some people after receiving their rilpivirine injection. Most symptoms resolved within a few minutes after the injection. Symptoms may include:
 - trouble breathing
 - stomach cramps
 - sweating
 - numbness of your mouth
 - feeling anxious
 - feeling warm
 - feeling light-headed or feeling like you are going to pass out (faint)
 - blood pressure changes
- **Liver problems.** People with a history of hepatitis B or C virus 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 CABENUVA treatment. 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 (jaundice)
 - dark or "tea-colored" urine
 - light-colored stools (bowel movements)
 - nausea or vomiting
 - loss of appetite
 - 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

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
- headache
- muscle or bone pain
- nausea
- sleep problems
- dizziness
- rash

These are not all the possible side effects of CABENUVA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

GET MORE INFORMATION

- Talk to your healthcare provider or pharmacist.
- Go to CABENUVA.com or call 1-877-844-8872, where you can also get FDA-approved labeling.

January 2021 CBN:1PIL

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CBROGM210040 June 2021

Produced in USA.