



**CABENUVA**

cabotegravir 200 mg/mL; rilpivirine 300 mg/mL  
extended-release injectable suspensions

***Heard about  
injectable CABENUVA?***

*Find out what you need to know.*



## **Every other month, and you're good to go.**

CABENUVA is given by a healthcare provider as 2 injections, initially 1 month apart for 2 months. Attend all appointments.

## **A different way to treat HIV.**

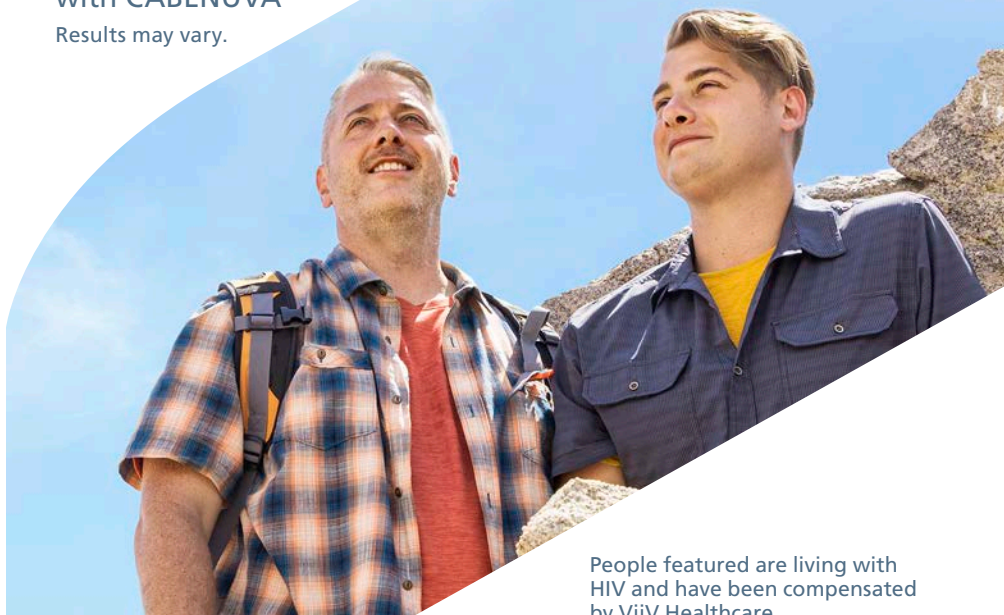


CABENUVA is not your every-day treatment. Unlike daily pills, it's a long-acting, complete HIV regimen you can get monthly or every other month.

### **Steve**

Hiker  
Avid traveler  
Stays undetectable  
with CABENUVA

Results may vary.



People featured are living with HIV and have been compensated by ViiV Healthcare.

## **What is CABENUVA?**

CABENUVA is a complete prescription regimen used to treat HIV-1 infection in people 12 years and older who weigh at least 77 lbs (35 kg), to replace their current HIV-1 medicines when their healthcare provider determines they meet certain requirements.

## **IMPORTANT SAFETY INFORMATION**

### **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); St John's wort (*Hypericum perforatum*).

### **What are the 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.

Please see Important Safety Information throughout and [click here](#) for Important Facts About CABENUVA.

## How is CABENUVA different?

It's an injectable treatment that **works continuously to help you stay undetectable\*** for up to 2 months, depending on the treatment plan.

With regular injections, **you won't have to take any more daily HIV pills.**<sup>†</sup>

***“Now that I only get my treatment 6 times a year, I don't have to worry about having to go home to take a pill.”***

**Jayson**  
Veteran  
History buff  
Stays undetectable  
with CABENUVA

Results may vary.

## IMPORTANT SAFETY INFORMATION (cont'd)

### What are the possible side effects of CABENUVA? (cont'd)

CABENUVA may cause serious side effects, including: (cont'd)

- **Post-injection reactions** have happened in some people within minutes after receiving their rilpivirine injection. Most symptoms resolved within minutes. Symptoms may include: trouble breathing; narrowing of airways; stomach cramps; sweating; numbness of the mouth; pain (eg, back and chest); feeling anxious; feeling warm; rash; feeling lightheaded or faint; blood pressure changes.
- **Liver problems.** People with a history of hepatitis B or C virus or with 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:** the skin or the white part of the eyes turns yellow (jaundice); dark or “tea-colored” urine; light-colored stools (bowel movements); nausea or vomiting; loss of appetite; pain, aching, or tenderness on the right side of the stomach area; itching.

\*Undetectable means the amount of HIV in the blood is below the level that can be measured by a lab test. Results may vary.

<sup>†</sup>Before your first injections, you may take daily starter pills for about a month to see how your body reacts.

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extended-release injectable suspensions

***“I work two jobs,  
so long-acting treatment  
really works with  
my lifestyle.”***

**Karen**

Lab technician

Proud mom

Stays undetectable  
with CABENUVA

Results may vary.



**[Click here to watch  
real stories from  
people like Karen.](#)**

**IMPORTANT SAFETY INFORMATION (cont'd)**

**What are the possible side effects of CABENUVA?  
(cont'd)**

CABENUVA may cause serious side effects, including: (cont'd)

- 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.

Please see Important Safety Information throughout and [click here](#) for Important Facts About CABENUVA.

## A flexible HIV treatment routine

CABENUVA injections can be given by a healthcare professional once a month or every other month, depending on your treatment plan.

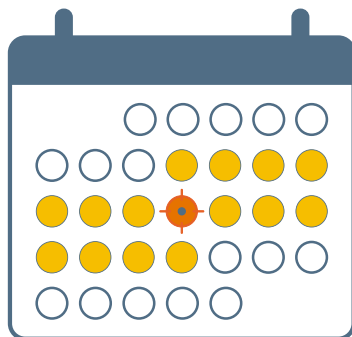
To help stay undetectable, it's important to keep all planned appointments.

### Target Treatment Date

You and your doctor will choose an ongoing date that works best for your injection appointments. This is called your **Target Treatment Date**. If you can't make your appointment, be sure to contact your doctor right away.

### Flexible Treatment Window

You have a **Flexible Treatment Window** to schedule your appointment within—from 7 days before to 7 days after your Target Treatment Date.



 Target Treatment Date

 Flexible Treatment Window

## IMPORTANT SAFETY INFORMATION (cont'd)

### 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 ever 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.

**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. **Do not start taking a new medicine without telling your healthcare provider.**

Please see Important Safety Information throughout and [click here](#) for Important Facts About CABENUVA.

## What the clinical studies show



**Long-acting CABENUVA is proven to help keep people undetectable.\***

CABENUVA was tested in 3 clinical studies, involving more than 2,200 undetectable people who either switched or continued their HIV regimen.

- In 2 studies, people received once-monthly CABENUVA or continued their daily pill regimen.<sup>†</sup>
- In the other study, people received CABENUVA injections every other month or once a month.

### At Week 48 in all studies:

- **9 out of 10 people** remained undetectable, whether they were on daily HIV pills or CABENUVA
- **Less than 2% of people** did not remain undetectable (primary endpoint)

### Results were consistent:

- With both once-monthly and every-other-month regimens
- Whether or not people took starter pills before beginning injections
- Across a diverse range of ages, races, and genders, including transgender people
- After 96 weeks

CABENUVA was also tested in **people 12 years and older who weigh at least 77 lbs (35 kg).**

\*Undetectable means the amount of HIV in the blood is below the level that can be measured by a lab test (less than 50 copies/mL). Results may vary.

<sup>†</sup>Daily pill regimens contained dolutegravir and 2 nucleoside reverse transcriptase inhibitors (NRTIs) or 2 NRTIs plus a protease inhibitor (PI), non-nucleoside reverse transcriptase inhibitor (NNRTI), or integrase strand transfer inhibitor (INSTI).

## IMPORTANT SAFETY INFORMATION (cont'd)

### How will I receive CABENUVA?

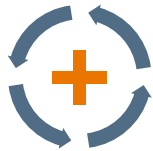
- Once a month or once every 2 months, a healthcare provider will inject CABENUVA as 2 injections (cabotegravir and rilpivirine), one into the muscle of each side of your buttocks.
- Before receiving your first CABENUVA injections, your healthcare provider may have you take 1 VOCABRIA (cabotegravir) tablet and 1 EDURANT (rilpivirine) tablet once a day for 1 month (at least 28 days) to assess how you tolerate these medicines.
- Stay under the care of a healthcare provider during CABENUVA treatment. It is important that you attend all planned injection appointments.
- If you miss or plan to miss a scheduled CABENUVA injection by more than 7 days, call your healthcare provider right away to discuss your treatment options.
- If you stop treatment with CABENUVA you will need to take other medicines to treat your HIV-1 infection and reduce the risk of developing viral resistance. Call your healthcare provider right away to discuss your treatment options.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Please read the Patient Information for CABENUVA and discuss it with your healthcare provider.

Please see Important Safety Information throughout and [click here](#) for Important Facts About CABENUVA.

## Side effects



**The most common side effects reported in all clinical studies were injection-site reactions.\***

- 75% to 83% of patients experienced injection-site reactions.

Overall, injection-site reactions lasted about 3 days and were mostly mild to moderate.

Injection-site reactions were reported less often the longer people were on treatment.†

**Aside from injection-site reactions, the most common side effects to occur in less than 9% of people were:**

- Fever
- Tiredness
- Headache
- Muscle or bone pain
- Nausea
- Sleep problems
- Dizziness
- Rash

Less than 4% of people on CABENUVA stopped treatment due to any side effect.‡

Results may vary.

\*Injection-site reactions include pain, tenderness, hardened mass or lump, swelling, redness, itching, bruising, and warmth at the injection site.

†The true rate of injection-site reactions over time may be underestimated, as symptoms that occurred may not have been reported during the study.

‡4% of people on once-monthly CABENUVA; 2% of people on every-other-month CABENUVA.

## IMPORTANT SAFETY INFORMATION

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- are taking certain medicines: carbamazepine; oxcarbazepine; phenobarbital; phenytoin; rifabutin; rifampin; rifapentine; dexamethasone (more than a single-dose treatment); St John's wort (*Hypericum perforatum*).

**What are the 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.

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## What people said about switching to CABENUVA



**9 out of 10 people** preferred the long-acting CABENUVA regimen they switched to over their previous regimen.\*†

In a survey conducted during clinical studies, people were asked how they felt about their treatment, including which one they preferred. The results are their opinions and don't imply clinical effectiveness.

**“HIV pills aren't on my mind anymore.”**

**Orlando**  
Fashionista  
Event planner  
Stays undetectable with CABENUVA

Results may vary.

\*88% of people said they preferred once-monthly CABENUVA over their previous daily HIV pills, 2% preferred daily HIV pills, and 10% did not respond to the survey question.

†94% of people with previous CABENUVA experience said they preferred injections every other month over their previous once-monthly injections or daily starter pills, 3% preferred once-monthly injections, 2% preferred daily starter pills, and 1% reported no preference.

‡98% of people with no previous CABENUVA use preferred injections every other month over daily starter pills, 1% preferred daily starter pills, and <1% reported no preference.

## IMPORTANT SAFETY INFORMATION (cont'd)

### What are the possible side effects of CABENUVA? (cont'd)

CABENUVA may cause serious side effects, including: (cont'd)

- **Post-injection reactions** have happened in some people within minutes after receiving their rilpivirine injection. Most symptoms resolved within minutes. Symptoms may include: trouble breathing; narrowing of airways; stomach cramps; sweating; numbness of the mouth; pain (eg, back and chest); feeling anxious; feeling warm; rash; feeling lightheaded or faint; blood pressure changes.
- **Liver problems.** People with a history of hepatitis B or C virus or with 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:** the skin or the white part of the eyes turns yellow (jaundice); dark or “tea-colored” urine; light-colored stools (bowel movements); nausea or vomiting; loss of appetite; pain, aching, or tenderness on the right side of the stomach area; itching.

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## ***Nobody knows you like you know you***

By discussing your treatment priorities with your doctor, you can find out if CABENUVA is right for you.

## ***Have the CABENUVA conversation with your doctor today.***

Here are some topics to help get you started:

***How you feel about taking daily HIV pills***

***What switching to a long-acting treatment would mean for you***

***If you're undetectable,\* how you can make the switch to CABENUVA***

### **Mark**

Nature enthusiast  
Adventurer  
Stays undetectable  
with CABENUVA

Results may vary.

\*Undetectable means the amount of HIV in the blood is below the level that can be measured by a lab test.

## **IMPORTANT SAFETY INFORMATION (cont'd)**

### **What are the possible side effects of CABENUVA? (cont'd)**

**CABENUVA may cause serious side effects, including: (cont'd)**

- 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.

Please see Important Safety Information throughout and [click here](#) for Important Facts About CABENUVA.

## Help paying for CABENUVA

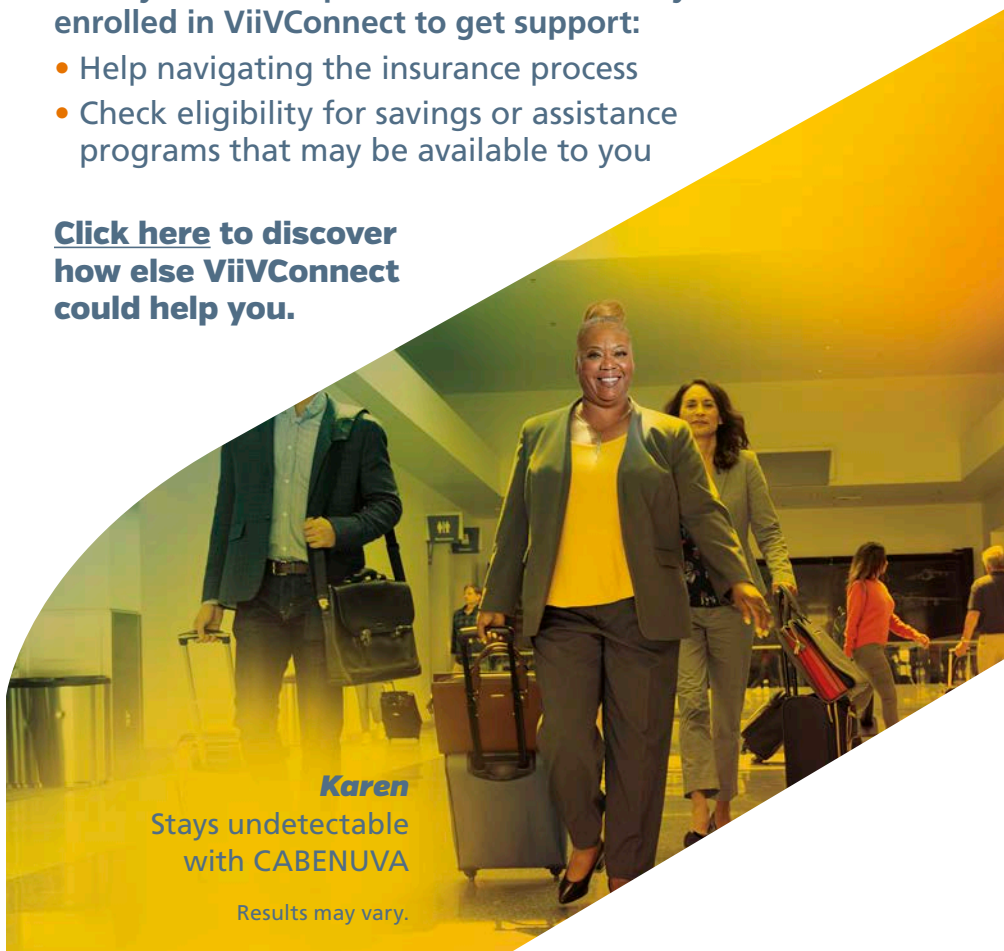
ViiVConnect can help you explore ways to pay for your prescribed ViiV Healthcare medications, **whether you're insured or not.**

If you qualify, your co-pay could be as little as \$0.<sup>a</sup>

Once your doctor prescribes CABENUVA, you can be enrolled in ViiVConnect to get support:

- Help navigating the insurance process
- Check eligibility for savings or assistance programs that may be available to you

**Click here to discover how else ViiVConnect could help you.**



## IMPORTANT SAFETY INFORMATION (cont'd)

### 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 ever 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.



Check out ways to access your prescribed ViiV Healthcare medications

Insurance Review

Financial Assistance Programs<sup>a</sup>

Call to speak to an Access Coordinator

Get support from ViiVConnect



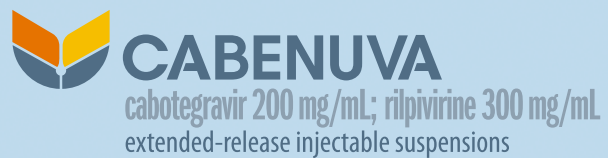
1-844-588-3288 (toll-free)  
Monday-Friday, 8AM-11PM (ET)

LEARN MORE

<sup>a</sup>Subject to eligibility and program terms and conditions; ViiVConnect programs do not constitute health insurance.

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Please see Important Safety Information throughout and [click here](#) for Important Facts About CABENUVA.



***Ask your doctor today if  
CABENUVA is right for you.***

**Visit [CABENUVA.com](https://www.cabenuva.com)**

## 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 people 12 years and older who weigh at least 77 lbs (35 kg), to replace their current HIV-1 medicines 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 younger than 12 years of age or weighing less than 77 lbs (35 kg).

### DO NOT RECEIVE CABENUVA IF YOU

- have ever had an allergic reaction to cabotegravir or rilpivirine.
- are taking the following medicines:
  - carbamazepine
  - oxcarbazepine
  - phenobarbital
  - phenytoin
  - rifabutin
  - rifampin
  - rifapentine
  - dexamethasone (more than a single-dose treatment)
  - 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 ever 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 minutes after the injection. Symptoms may include:
  - trouble breathing
  - narrowing of airways
  - stomach cramps
  - sweating
  - numbness of your mouth
  - pain (e.g., back and chest)
  - feeling anxious
  - feeling warm
  - rash
  - 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, aching, 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.

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