ABOUT CABENUVA HOW TO SCHEDULE SIDE EFFECTS GETTING STARTED MORE INFO



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

Learn about CABENUVA.

CABENUVA is given every other month or monthly by a healthcare provider as two injections, after you take about a month of once-daily starter pills. Your every other month regimen begins after two consecutive months of injections. It's important to attend all appointments.

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

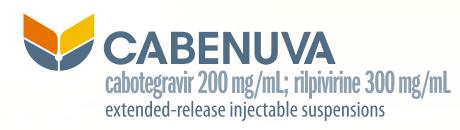
#### What is CABENUVA?

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





## ABOUT CABENUVA

"Instead of taking my HIV pill every day,
I get CABENUVA just once every other
month. That's only 6 times a year."

Veteran | History buff Stays undetectable with CABENUVA Results may vary.

## IMPORTANT SAFETY INFORMATION (cont'd)

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.







## How is CABENUVA different?

## Instead of an HIV treatment you take every day, CABENUVA is:



An injectable treatment you can get every other month



A long-acting, complete HIV treatment



Proven to help keep people undetectable\* for up to 2 months, depending on the treatment plan

\*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.

## **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 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 (eg, back and chest); feeling anxious; feeling warm; rash; feeling lightheaded or like you are going to faint; blood pressure changes.







# Could CABENUVA be a good fit for you? If you're undetectable, think about the following:



What are your challenges with taking daily HIV pills?



What would switching to long-acting treatment mean for you?



Can you commit to regular treatment appointments?

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

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

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

• 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.







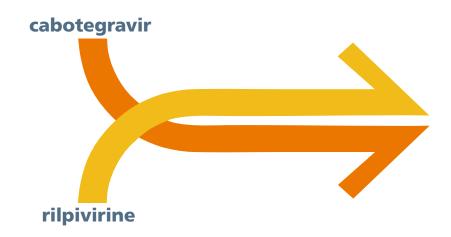
**NEXT** 

## **How does CABENUVA work?**



It contains 2 HIV medicines, cabotegravir and rilpivirine, to help keep you undetectable.\*

These 2 medicines slowly release over time to keep around the same level of medicine in your body between appointments.



## **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.







<sup>\*</sup>Results may vary.



See next page for how to schedule CABENUVA treatment.

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

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.







## How do you schedule CABENUVA treatment?



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

To help stay undetectable, it's important to keep your planned appointments and stick to your treatment plan.



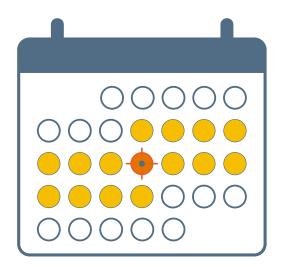
## **Target Treatment Date**

- The ongoing date you and your doctor choose for your regular injection appointments
- If you can't make your appointment, be sure to contact your doctor right away



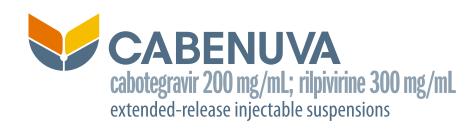
## Flexible Treatment Window

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



# IMPORTANT SAFETY INFORMATION (cont'd) Before you receive 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.







**NEXT** 

## SIDE EFFECTS

"After my injection I was sore, but the next day I didn't have to take my HIV pill."

In clinical studies, injection-site reactions were the most common side effects.

## Mark

Nature enthusiast | Adventurer Stays undetectable with CABENUVA

Results may vary.

## IMPORTANT SAFETY INFORMATION (cont'd)

Before you receive CABENUVA, tell your healthcare provider about all your medical conditions, including if you: (cont'd)

- 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.









## What are the most common side effects?

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



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

Most injection-site reactions were mild to moderate.

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

Results may vary.

\*CABENUVA was tested in 3 clinical studies, involving more than 2,000 undetectable adults who either switched or continued their HIV regimen.

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

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

**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.







## What are the most common side effects?

# Aside from injection-site reactions, the most common side effects included:

- Fever
- Tiredness
- Headache
- Muscle or bone pain

- Nausea
- Sleep problems
- Dizziness
- Rash



## These common side effects occurred in less than 9% of people in clinical studies.\*

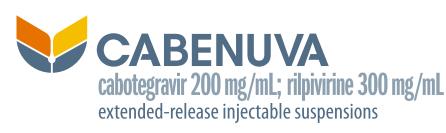
Results may vary.

\*CABENUVA was tested in 3 clinical studies, involving more than 2,000 undetectable adults who either switched or continued their HIV regimen.

## **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 will have you take one VOCABRIA (cabotegravir) tablet and one EDURANT (rilpivirine) tablet once a day for 1 month (at least 28 days) to assess how well 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.









## 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 steps to getting started?



## READY

**Verify coverage and costs** 

## Take starter pills

If you're prescribed CABENUVA, your doctor's office and ViiVConnect can help confirm your insurance coverage and any out-of-pocket costs.

SET

Before beginning your regular injections, you'll take 2 starter pills once a day with a meal for about a month to see how your body responds to the 2 medicines in CABENUVA.

## GO

### **Begin long-acting CABENUVA**

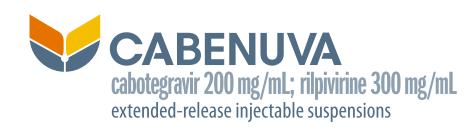
You'll get your injections on or around your Target Treatment Date, according to your treatment plan. Your last dose of starter pills will be on the same day as your first treatment.

## **Get started now**

## IMPORTANT SAFETY INFORMATION (cont'd) 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.







## How can you learn more about getting started?

## Watch our step-by-step video!

Getting started on CABENUVA is a different kind of journey, so we created a special video to walk you through each of the 3 steps:

Ready, Set, Go!

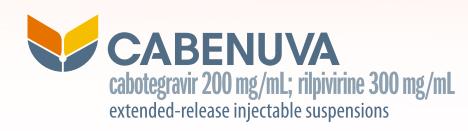




## **IMPORTANT SAFETY INFORMATION (cont'd)**

What are the possible side effects of CABENUVA? (cont'd) CABENUVA may cause serious side effects, including: (cont'd)

• Post-injection reactions have happened 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 (eg, back and chest); feeling anxious; feeling warm; rash; feeling lightheaded or like you are going to faint; blood pressure changes.











## Can you get 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're prescribed CABENUVA, you can enroll in ViiVConnect to:



Get help navigating the insurance process



Find out if you're eligible for the CABENUVA Savings Program that may help lower your out-of-pocket costs

If approved, your co-pay could be as little as \$0.\*

## For more information:

- Visit ViiVConnect.com
- Call 844-588-3288 (toll free)—Monday-Friday, 8AM-11PM (ET)
- Multilingual options available

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

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

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

• 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.







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

## **MORE INFO**

"I have that regular contact with my medical team, so I've built a dynamic and ongoing relationship."

## Steve

Hiker | Avid traveler 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)

 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.







# Continuing the CABENUVA conversation

Here are a few other questions that may come up:

## Q. How does CABENUVA keep people undetectable?

**A.** CABENUVA combines 2 HIV medicines that control the virus in different ways. These medicines are long-acting, so they can be given once a month or every other month.

## Q. What if I miss my CABENUVA injection?

**A.** If you miss or plan to miss your treatment appointment by more than 7 days, contact your doctor right away to discuss your treatment options to ensure you stay undetectable.

## Q. Can I switch my dosing schedule if I'm already on CABENUVA?

**A.** If you're already on CABENUVA, you may be able to switch your dosing schedule, either to every other month or monthly injections. The best way to find out is to ask your doctor—they can advise you on the steps you'll need to take.

Continued on next page

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

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

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.







# Continuing the CABENUVA conversation

## Q. What can I do to help treat injection-site reactions?

**A.** In clinical trials, injection-site reactions\* were common and most were mild to moderate. Ask your doctor what you can do to help treat symptoms like soreness or irritation you may experience from the injections.



## Q. Are there drug interactions with CABENUVA?

**A.** Some medicines may interact with CABENUVA, so be sure to tell your doctor about all the medicines you may be taking. These include all prescription and over-the-counter medications, vitamins, and herbal supplements. Do not start taking a new medicine without telling your doctor.

## Q. When can I start my long-acting injections?

**A.** Before beginning CABENUVA injections, you will take about a month of once-daily starter pills. Your first and second injections will be one month apart. After that, you will begin your monthly or every other month regimen.

**Continued on next page** 

## IMPORTANT SAFETY INFORMATION (cont'd)

Before you receive 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.







# Continuing the CABENUVA conversation

## Q. What do I need to do before I begin taking starter pills?

- **A.** You should contact your doctor's office to confirm:
  - When to stop your current HIV medication
  - When to begin taking starter pills
  - Your first injection appointment

## Q. How are starter pills delivered?

**A.** Starter pills are delivered in a Welcome Pack to your preferred location—such as your home or your doctor's office.

## Q. What are the costs for CABENUVA and how much will I pay?

**A.** The costs are for the treatment itself and the doctor appointments. The amount you pay out of pocket depends on your insurance coverage and if you qualify for any programs that may lower out-of-pocket costs.

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

Before you receive CABENUVA, tell your healthcare provider about all your medical conditions, including if you: (cont'd)

- 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.







## **Get going at <u>CABENUVA.com</u>**

Watch real stories, find resources, get answers to FAQs, and more

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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

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## 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 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

- o blisters or sores in mouth
- o generally ill feeling
- blisters
- o tiredness
- redness or swelling of the eyes
- muscle or joint aches trouble breathing
- 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
- · feeling anxious
- narrowing of airways
- feeling warm
- stomach cramps
- rash
- sweating numbness of your mouth
- o feeling light-headed or feeling like you are going to pass out (faint)
- pain (e.g., back and chest)
- 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)
  - o dark or "tea-colored" urine
  - light-colored stools (bowel movements)
  - nausea or vomiting
  - · loss of appetite
  - o pain, aching, or tenderness on the right side of your stomach area
- 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
- · have thoughts of hurting yourself
- feeling anxious or restless
- (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
- muscle or bone pain nausea

sleep problems

dizziness

- fever
- tiredness

rash

• headache

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.

February 2022 CBN:1PIL

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