# Once a month, and you're good to go. Learn about CABENUVA.

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

Every person featured in this brochure has been compensated by ViiV Healthcare. Results may vary.

#### 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), and/or
- St John's wort
- (Hypericum perforatum)

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

Please see Important Safety Information throughout. Click to see Important Facts About CABENUVA.

# **ABOUT CABENUVA**

"Now that I'm on CABENUVA, I don't have to think about taking HIV pills every day."

#### **Jakub** 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

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



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# How is CABENUVA different?

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



\*You'll take about a month of once-daily starter pills before beginning CABENUVA. Stay under the care of your doctor during treatment. <sup>†</sup>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 a few minutes after the injection.
- Symptoms may include:
- trouble breathing
- stomach cramps
- sweating

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ВАСК

- numbness of vour mouth
- feeling anxious
- feeling warm
- feeling light-headed or feeling
- like you are going to pass out (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 once-monthly treatment mean for you?



Can you commit to monthly 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
- nausea or vomiting
- loss of appetite
   pain or tenderness on
- yellow (jaundice)
- dark or "tea-colored" urine
- light-colored stools (bowel movements)
- the right side of your
- stomach area
- itching

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

Please see Important Safety Information throughout. Click to see Important Facts About CABENUVA.

NEXT

# How does CABENUVA work?



# It contains 2 HIV medicines, cabotegravir and rilpivirine, to keep you undetectable.\* These 2 medicines slowly release over time to keep around the same level of medicine in your body between

rilpivirine

\*Results may vary.

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BACK

#### 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

monthly appointments.

 have thoughts of hurting yourself (suicide) or have tried to hurt yourself



# **MONTHLY SCHEDULE**

"Once-monthly CABENUVA gives me flexibility. It really works with my schedule."

#### Orlando

Stavs undetectable with CABENUVA Results may vary.

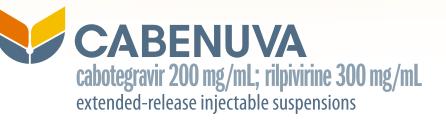
See next page for how to schedule monthly treatment.

#### **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
- headache
- muscle or bone pain
- nausea
- fever
- tiredness

- 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 monthly treatment?





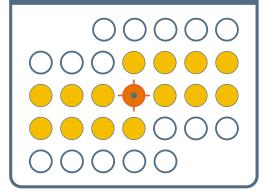
### **Target Treatment Date**

- The day you and your doctor choose to schedule injections each month
- It's important to meet this date every month
- If you can't make this date, contact your doctor right away

## **Flexible Treatment Window**

 You have a Flexible Treatment Window from 7 days before to 7 days after your Target Treatment Date

#### CABENUVA CALENDAR



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

#### **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 or have had liver problems, including hepatitis B or C infection.
- have ever had mental health problems.



# **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. Results may vary. *Mark* Stays undetectable with CABENUVA

#### **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.



**SIDE EFFECTS** 

# What are the most common side effects?



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

of people experienced injection-site reactions

99%

were mild to moderate

Results may vary.

\*CABENUVA was tested in 2 clinical studies over a 48-week period, where more than 1,000 adults either switched to CABENUVA or continued their current daily pill regimens.

<sup>†</sup>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 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.



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# 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 2 clinical studies over a 48-week period, where more than 1,000 adults either switched to CABENUVA or continued their current daily pill regimens.

## IMPORTANT SAFETY INFORMATION (cont'd)

#### How will I receive CABENUVA?

- Once a month, a healthcare provider will inject CABENUVA as 2 injections (cabotegravir and rilpivirine), one into 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 one month (at least 28 days) to assess how well you tolerate these medicines.
- Stay under the care of a healthcare provider during treatment with CABENUVA. It is important that you attend your planned appointments to receive your injections.
- If you miss or plan to miss a scheduled monthly CABENUVA injection by more than 7 days, call your healthcare provider right away to discuss your treatment options.



**CABENUVA** 





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SIDE EFFECTS

# GETTING STARTED

"In my experience, I can get my injections during my lunch break-my doctor gets me in and out most days."

Mark Stays undetectable with CABENUVA

Appointment times may vary. You may be asked to wait about 10 minutes after your treatment, to see how your body responds. Results may vary.

#### **IMPORTANT SAFETY INFORMATION**

#### Do not receive CABENUVA if you:

- have ever had an allergic reaction to cabotegravir or rilpivirine.
- are taking certain medicines:
  - rifapentine
  - dexamethasone
  - (more than a single-dose
- phenytoin

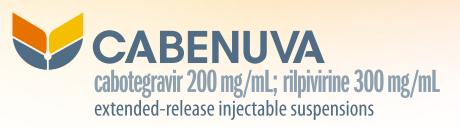
carbamazepine

oxcarbazepine

phenobarbital

- rifabutin
- rifampin
- St John's wort
- (Hypericum perforatum)

treatment), and/or



# What are the steps to getting started?



#### READY

#### Verify coverage and costs

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

#### SET

#### Take starter pills

Before beginning monthly 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 once-a-month CABENUVA

You'll receive your injections around the same day every month. You'll take the last dose of starter pills on the same day as your first CABENUVA 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

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





# 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 a few minutes after the injection.

Symptoms may include:

- trouble breathing
- stomach cramps
- sweating

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- numbness of your mouth
- feeling anxious
- feeling warm
- feeling light-headed or feeling like you are going to pass out (faint)
- blood pressure changes



Find out if you're eligible

for programs that may help lower out-of-pocket costs



ViiVConnect is a program that can help you explore ways to pay for your prescribed ViiV Healthcare medication, whether you're insured or uninsured.\*

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



Determine your insurance coverage

#### For more information:

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

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

#### 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 or tenderness on the right side of your stomach area
- itching





# **MORE INFO**

"I look forward to that monthly visit because I have that personal connection with my healthcare team."



Jayson 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



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# **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.

#### Q. What if I miss my monthly 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.

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, • muscle or bone pain itching, bruising, and warmth at the injection site
- headache

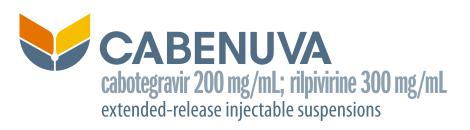
  - nausea

sleep problems

- fever
- tiredness

- 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.





Please see Important Safety Information throughout. Click to see Important Facts About CABENUVA.

# 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.

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

#### 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.

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 or have 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 monthly 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.





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# 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 0
- о 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: · blisters or sores in mouth

blisters

- fever
- generally ill feeling
- tiredness
- muscle or joint aches
- redness or swelling of the eyes • swelling of the mouth, face, lips,
- or tongue
- trouble breathing 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
- feeling warm feeling light-headed or feeling like
- stomach cramps 0 sweating

0

- you are going to pass out (faint)
- numbness of your mouth blood pressure changes
- feeling anxious
- 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)
  - 0 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 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,
- fever
- tiredness
- ٠ 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.

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nausea

dizziness

rash

## muscle or bone pain

- bruising, and warmth at the injection site sleep problems