

**ASO  
PRO**

***It's time.  
A different way  
to treat HIV.***

***Once a month,  
and your clients are  
good to go.***

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



**Jakub**

Stays undetectable  
with CABENUVA

Results may vary.

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

ASO Pro = AIDS Service Organization Professional

## INDICATION

CABENUVA is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

- Do not use CABENUVA in patients with previous hypersensitivity reaction to cabotegravir or rilpivirine
- Do not use CABENUVA in patients receiving carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, systemic dexamethasone (>1 dose), and St John's wort

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.

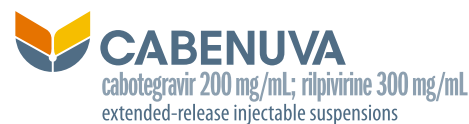


**CABENUVA**

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

**As an ASO Professional,  
you offer your clients so much.**

**You can now tell them about  
a change in how HIV is treated:**



## **CABENUVA**

**CABENUVA is the first and only complete,  
injectable HIV treatment given once  
every month.**

***Instead of taking daily HIV  
treatment, your clients can stay  
undetectable\* with 1 treatment  
every month.***

\*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).

**Michelle**  
Undetectable  
since 1998

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

#### **WARNINGS AND PRECAUTIONS**

##### **Hypersensitivity Reactions:**

- Hypersensitivity reactions, including cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), have been reported during postmarketing experience with rilpivirine-containing regimens. While some skin reactions were accompanied by constitutional symptoms such as fever, other skin reactions were associated with organ dysfunctions, including elevations in hepatic serum biochemistries
- Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with CABENUVA
- Discontinue CABENUVA immediately if signs or symptoms of hypersensitivity reactions develop. Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated. Prescribe the oral lead-in prior to administration of CABENUVA to help identify patients who may be at risk of a hypersensitivity reaction



## Asking about CABENUVA

Help your clients keep their doctor informed by encouraging them to speak openly about their treatment priorities.

These topics can help your client and their doctor determine if CABENUVA is a good fit.

- 1 **How taking daily HIV pills impacts your lifestyle**
- 2 **What switching to a once-monthly treatment would mean for you**
- 3 **If you're undetectable, how you can make the switch to CABENUVA**

See more conversation starters at [CABENUVA.com](https://CABENUVA.com)



### CABENUVA cost support

- ViiVConnect can help explore ways to pay for prescribed ViiV Healthcare medications, with or without insurance.
- If prescribed CABENUVA, enrolling in ViiVConnect can help with:
  - Determining insurance coverage
  - Finding out eligibility for programs that may help lower out-of-pocket costs\*

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

Learn more at [ViiVConnect.com/injectable](https://ViiVConnect.com/injectable)

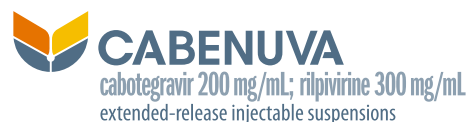
**See last page for more information about switching to CABENUVA**

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### Post-Injection Reactions:

- Serious post-injection reactions (reported in less than 1% of subjects) were reported within minutes after the injection of rilpivirine, including dyspnea, agitation, abdominal cramping, flushing, sweating, oral numbness, and changes in blood pressure. These events may have been associated with inadvertent (partial) intravenous administration and began to resolve within a few minutes after the injection
- Carefully follow the Instructions for Use when preparing and administering CABENUVA to avoid accidental intravenous administration. Observe patients briefly (approximately 10 minutes) after the injection.



**"CABENUVA really works with my schedule."**

#### Orlando

Stays undetectable with CABENUVA

Results may vary.

**Hear more from real people on CABENUVA at [CABENUVA.com/real-stories](https://CABENUVA.com/real-stories)**

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

If a post-injection reaction occurs, monitor and treat as clinically indicated

#### Hepatotoxicity:

- Hepatotoxicity has been reported in patients receiving cabotegravir or rilpivirine with or without known pre-existing hepatic disease or identifiable risk factors
- Patients with underlying liver disease or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations
- Monitoring of liver chemistries is recommended and treatment with CABENUVA should be discontinued if hepatotoxicity is suspected

**Once-a-month CABENUVA is proven to be as effective as daily HIV pills at keeping people undetectable.\*\*†**

**CABENUVA was tested in 2 clinical studies:**

With more than 1,000 adults

Over a 48-week period

**People were already undetectable and divided into 2 equal groups:**

Those who switched to CABENUVA

Those who continued on their current daily pill regimen\*

#### At Week 48:

- **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]

\*Daily pill regimens tested contained dolutegravir and 2 nucleoside reverse transcriptase inhibitors (NRTIs) or 2 NRTIs plus a protease inhibitor (PI), NNRTI (non-nucleoside reverse transcriptase inhibitor) or INSTI (integrase strand inhibitor).

†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.

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

## Side effects

The most common side effects reported in clinical studies were injection-site reactions.<sup>§</sup>

**83%**

of people in the clinical studies experienced injection-site reactions.

**99%**

of injection-site reactions were mild to moderate.

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

Side effect	Switched to CABENUVA	Continued on daily pill regimen*
Fever	8%	0%
Tiredness	5%	<1%
Headache	4%	<1%
Muscle or bone pains	3%	<1%
Nausea	3%	1%
Sleep problems	2%	<1%
Dizziness	2%	<1%
Rash	2%	0%

**4%**

of people on CABENUVA stopped treatment due to any side effect.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### Depressive Disorders:

- Depressive disorders (including depressed mood, depression, major depression, mood altered, mood swings, dysphoria, negative thoughts, suicidal ideation or attempt) have been reported with CABENUVA or the individual products
- Promptly evaluate patients with depressive symptoms

#### Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions:

- The concomitant use of CABENUVA and other drugs may result in known or potentially significant drug interactions (see Contraindications and Drug Interactions)

- Rilpivirine doses 3 and 12 times higher than the recommended oral dosage can prolong the QTc interval. CABENUVA should be used with caution in combination with drugs with a known risk of Torsade de Pointes

#### Long-Acting Properties and Potential Associated Risks with CABENUVA:

- Residual concentrations of cabotegravir and rilpivirine may remain in the systemic circulation of patients for prolonged periods (up to 12 months or longer). Select appropriate patients who agree to the required monthly injection dosing schedule because non-adherence to monthly injections or missed doses could lead to loss of virologic response and development of resistance



**9 out of 10 people who switched to CABENUVA preferred once-a-month injections over their daily pill regimen\*†**

In a survey conducted during clinical studies, patients were asked to share their perspectives on their treatments. The results are participant opinions and don't imply clinical effectiveness.

## Scheduling a monthly appointment

### Target Treatment Date

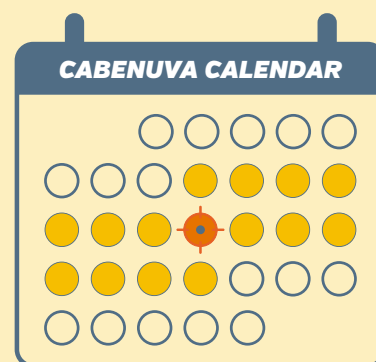
Your clients and their doctor will choose one day a month to get their injections. That's called a **Target Treatment Date**. It's important to meet this date each month.

If your clients can't make their **Target Treatment Date**, they should be sure to contact their doctor right away.

### Flexible Treatment Window

Your clients will have a **Flexible Treatment Window**—from 7 days before to 7 days after their Target Treatment Date.

Be sure to remind your clients that to help stay undetectable, it's important for them to keep their monthly appointments and stick with their treatment plan.



\*Daily pill regimens tested contained dolutegravir and 2 nucleoside reverse transcriptase inhibitors (NRTIs) or 2 NRTIs plus a protease inhibitor (PI), NNRTI (non-nucleoside reverse transcriptase inhibitor) or INSTI (integrase strand inhibitor).  
†88% of people said they preferred CABENUVA, 2% preferred previous regimen, and 10% did not respond. Results may vary.

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS (cont'd)

#### Long-Acting Properties and Potential Associated Risks with CABENUVA: (cont'd)

- To minimize the potential risk of developing viral resistance, it is essential to initiate an alternative, fully suppressive antiretroviral regimen no later than 1 month after the final injection doses of CABENUVA. If virologic failure is suspected, switch the patient to an alternative regimen as soon as possible

### ADVERSE REACTIONS

The most common adverse reactions (incidence  $\geq 2\%$ , all grades) with CABENUVA were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash.

### DRUG INTERACTIONS

- Refer to the applicable full Prescribing Information for important drug interactions with CABENUVA, VOCABRIA, or EDURANT
- Because CABENUVA is a complete regimen, coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
- Drugs that are strong inducers of UGT1A1 or 1A9 are expected to decrease the plasma concentrations of cabotegravir. Drugs that induce or inhibit CYP3A may affect the plasma concentrations of rilpivirine
- CABENUVA should be used with caution in combination with drugs with a known risk of Torsade de Pointes

# 3 steps to making the switch

If your clients are interested in switching to CABENUVA, their doctor's office can help them complete these 3 steps.

## READY

### Verify coverage and costs

If your clients are prescribed CABENUVA, their doctor's office and ViiVConnect can help confirm their insurance coverage and any out-of-pocket costs so they can begin their switch to CABENUVA.

## SET

### Take starter pills

Before beginning monthly injections, your clients will take 2 starter pills once a day for about a month. This is to see how their body responds to the 2 medicines in CABENUVA.

## GO

### Once-a-month CABENUVA

They will receive their injectable treatment around the same day every month. To help stay undetectable, it is important that your clients keep their monthly treatment appointments and stick to their treatment plan.

Remember, while your clients are on their regular monthly injections, they won't have to take any more pills to treat their HIV.

**For more ASO resources, visit [CABENUVA.com/aids-service-organizations/](https://CABENUVA.com/aids-service-organizations/)**

## IMPORTANT SAFETY INFORMATION (cont'd)

### USE IN SPECIFIC POPULATIONS

- **Pregnancy:** There are insufficient human data on the use of CABENUVA during pregnancy to adequately assess a drug-associated risk for birth defects and miscarriage. Discuss the benefit-risk of using CABENUVA during pregnancy and conception and consider that cabotegravir and rilpivirine are detected in systemic circulation for up to 12 months or longer after discontinuing injections of CABENUVA. An Antiretroviral Pregnancy Registry has been established
- **Lactation:** The CDC recommends that HIV-1-infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection. Breastfeeding is also not recommended due to the potential for developing viral resistance in HIV-positive

infants, adverse reactions in a breastfed infant, and detectable cabotegravir and rilpivirine concentrations in systemic circulation for up to 12 months or longer after discontinuing injections of CABENUVA

To report suspected adverse reactions, contact ViiV Healthcare at 1-877-844-8872 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](https://www.fda.gov/medwatch).

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.

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Comprehensive patient support programs and resources for healthcare providers

Benefits Verification

Prior Authorization  
and Appeals Support

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.



**CABENUVA**

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



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CBROGM210060 June 2021  
Produced in USA.