

# Ready for something different?

## Every other month, and your clients are **good to go.**

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

**Jayson**  
On CABENUVA

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

### INDICATION

CABENUVA is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/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

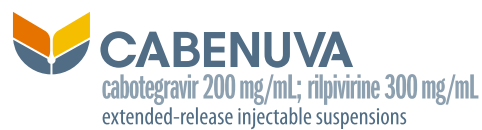
Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.



**CABENUVA**

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

***It's good to talk to your clients about their treatment options, including how to treat their HIV without daily pills.\****



## ***Could CABENUVA make a difference to your clients?***

Unlike daily HIV pills, CABENUVA is a **long-acting, complete HIV regimen** your clients can get monthly or every other month.

It's an injectable treatment that **works continuously to help your clients stay undetectable<sup>†</sup> for up to 2 months**, depending on their treatment plan.



**It's not your every-day treatment**

### ***Karen***

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

\*Before your first injections, you may take daily starter pills for about a month to see how your body reacts.

<sup>†</sup>Undetectable means the amount of HIV in the blood is below the level that can be measured by a lab test. Results may vary.

## **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. Cabotegravir and rilpivirine oral lead-in may be used to help identify patients who may be at risk of a hypersensitivity reaction



**“CABENUVA gives me flexibility. It 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://www.cabenuva.com/real-stories)

**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, bronchospasm, agitation, abdominal cramping, rash/urticaria, dizziness, flushing, sweating, oral numbness, changes in blood pressure, and pain (e.g., back and chest). These events may have been associated with accidental intravenous administration and began to resolve within a few minutes after the injection
- Carefully follow the Instructions for Use when preparing and administering CABENUVA. The suspensions should be injected slowly via intramuscular injection and avoid accidental intravenous administration. Observe patients briefly (approximately 10 minutes) after the injection. If a post-injection reaction occurs, monitor and treat as clinically indicated



### 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 they feel about taking daily HIV pills**
- 2 What switching to a long-acting treatment would mean for them**
- 3 If they're undetectable, how they can make the switch to CABENUVA**

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



### Help paying for CABENUVA

ViiVConnect can help explore ways to pay for prescribed ViiV Healthcare medications, whether your client is insured or not.

If your client qualifies, their co-pay could be as little as \$0.\*

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

- Help navigating the insurance process
- Check eligibility for savings or assistance programs

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

Learn more about [ViiVConnect.com](https://www.viivconnect.com)

#### 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



### 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 adults 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).**

## 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



### 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.<sup>§</sup>

**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.<sup>||</sup>

Results may vary.

\*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).

<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).

<sup>‡</sup>Injection-site reactions include pain, tenderness, hardened mass or lump, swelling, redness, itching, bruising, and warmth at the injection site.

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

<sup>||</sup>4% of people on once-monthly CABENUVA; 2% of people on every-other-month CABENUVA.

#### 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



**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, patients were asked to share their perspectives on their treatments. The results are participant opinions and don't imply clinical effectiveness.

## 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.

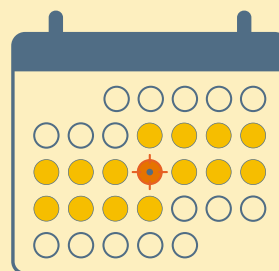
To help stay undetectable, it's important to keep all planned appointments.

### Target Treatment Date


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

### Flexible Treatment Window

Your client has a **Flexible Treatment Window** to schedule their appointment within—from 7 days before to 7 days after their Target Treatment Date.



 **Target Treatment Date**

 **Flexible Treatment Window**

\*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)

### WARNINGS AND PRECAUTIONS (cont'd)

#### 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 or every-2-month injection dosing schedule because non-adherence could lead to loss of virologic response and development of resistance
- 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 when dosed monthly and no later than 2 months after the final injections of CABENUVA when dosed every 2 months. If virologic failure is suspected, switch the patient to an alternative regimen as soon as possible

### ADVERSE REACTIONS

- The most common adverse reactions in adults (incidence  $\geq 2\%$ , all grades) treated with CABENUVA were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash
- The safety of CABENUVA in adolescents is expected to be similar to adults

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 client is 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****Prepare for their treatment plan**

Your client and their doctor will choose a Target Treatment Date for all ongoing injection appointments and set up their first one. Before beginning injections, they may take about a month of starter pills to see how their body reacts.

**GO****Begin long-acting CABENUVA**

Your client will get their injections on or around their Target Treatment Date, according to their treatment plan. To help stay undetectable, it's important to keep all planned appointments.

**To watch our step-by-step video, visit [CABENUVA.com/getting-started](https://CABENUVA.com/getting-started)**

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

- Refer to the applicable full Prescribing Information for important drug interactions with CABENUVA, VOCABRIA (cabotegravir), or EDURANT (rilpivirine)
- 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 UGT1A9 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

**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

**CABENUVA**

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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).

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

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.



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