

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

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

CABENUVA is given every other month or monthly by a healthcare provider as two injections, after your clients take about a month of once-daily starter pills. Their 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.

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



As an ASO Professional, it's important to talk to your clients about their treatment options.



You can now tell them about a different way to treat HIV than with daily pills.

CABENUVA

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



It's an injectable treatment proven to help keep people undetectable* for up to 2 months, depending on the treatment plan.

With regular injections, your clients won't have to take any more daily HIV pills.

*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).

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.



How they feel about taking daily HIV pills

What switching to a long-acting treatment would mean for them

If they're undetectable, how they can make the switch to CABENUVA

See more conversation starters at CABENUVA.com

ViiVConnect

Help paying for CABENUVA

- ViiVConnect can help explore ways to pay for prescribed ViiV Healthcare medications, whether your client is insured or not.
- If prescribed CABENUVA, enrolling in ViiVConnect can help with:
 - Navigating the insurance process
 - Finding out eligibility for the CABENUVA Savings
 Program that may help lower out-of-pocket costs.
 If approved, the co-pay could be as little as \$0.*

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

Learn more about ViiVConnect.com

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 inadvertent (partial) intravenous administration and began to resolve within a few minutes after the injection



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



Hear more from real people on CABENUVA at CABENUVA.com/real-stories

 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



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 2,000 undetectable adults who either switched or continued their HIV regimen.

In two	About 1,000 people received
48-week	once-monthly CABENUVA or
studies	continued their daily pill regimen.

In anotherAbout 1,000 people received48-weekCABENUVA injections every otherstudymonth or once a month.

All studies included a **diverse range of participants** across age, race, and gender, including transgender people.

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)

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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

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

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.

Most injection-site reactions were mild to moderate.

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

Fever

- Nausea
- TirednessHeadache
- Sleep problems
 Dizziness
- Muscle or bone pain
- Rash

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

Results may vary.

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



9 out of **10** people preferred the longacting 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.

Scheduling CABENUVA treatment

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

To help stay undetectable, it's important for them to keep their planned appointments and stick with their treatment plan.

Target Treatment Date

Your clients and their doctor will choose an ongoing date that works best to get their injections from a healthcare professional. That's called a **Target Treatment Date**. If your clients can't make their Target Treatment Date, they should be sure to contact their doctor right away.

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

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



*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 said they preferred injections every other month over their previous once-monthly injections or daily starter pills, 3% preferred daily starter pills, and 3% 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 nonadherence 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 (incidence ≥2%, all grades) with CABENUVA were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash
- The most common injection site reactions (grades 1-3, ≥1%) were pain/discomfort, nodules, induration, swelling, erythema, pruritus, bruising/discoloration, warmth, and hematoma

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



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 CABENUVA 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. **Begin long-acting CABENUVA**

GO

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

For more ASO resources, visit CABENUVA.com/aids-service-organizations/

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS (cont'd)

- 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

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.

Please see Important Safety Information throughout and <u>click here</u> for full Prescribing Information.

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ViiVConnect

Comprehensive patient support programs and resources for healthcare providers

Benefits Verification

Prior Authorization and Appeals Support Financial Assistance Programs^a Cet support from ViiVConnect

Call to speak to an Access Coordinator 1-844-588-3288 (toll-free)

Monday-Friday, 8AM-11PM (ET)

LEARN MORE

^aSubject to eligibility and program terms and conditions; ViiVConnect programs do not constitute health insurance.





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