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

Dosing and Administration Guide

A comprehensive review of the dosing options for CABENUVA

Please click here for full Prescribing Information, including Instructions for Use, for CABENUVA.

Introduction

CABENUVA is an every-2-month or once-monthly complete injectable regimen

- CABENUVA is a 2-drug, co-packaged product consisting of:
  - cabotegravir, an HIV-1 INSTI
  - rilpivirine, an HIV-1 NNRTI
- For every-2-month CABENUVA:
  - Patients will receive 3-mL initiation injections (600 mg/900 mg) for 2 consecutive months, followed by every-2-month 3-mL continuation injections (600 mg/900 mg) thereafter
- For once-monthly CABENUVA:
  - Patients will receive 3-mL initiation injections (600 mg/900 mg), followed by once-monthly 2-mL continuation injections (400 mg/600 mg) thereafter
- CABENUVA is for healthcare professional administration only

THIS GUIDE WILL PROVIDE INFORMATION ON:

- CABENUVA dosing kits and storage
- Setting a Target Treatment Date that works for you and your patients
- The CABENUVA dosing schedules
- Managing missed injections
- Considerations prior to injections
- Preparing and administering injections for CABENUVA dosing options
- Frequently asked questions

INSTI=integrase strand transfer inhibitor; NNRTI=non-nucleoside reverse transcriptase inhibitor.

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 additional Important Safety Information for CABENUVA throughout.
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extended-release injectable suspensions

How CABENUVA is supplied and stored

CABENUVA is available in 2 separate dosing kits, co-packaged as follows[1]:

CABENUVA 600-mg/900-mg (3-mL) kit

- For use in every-2-month initiation injections, every-2-month continuation injections, and once-monthly initiation injections
- One single-dose vial containing 600 mg/3 mL of cabotegravir extended-release injectable suspension
- One single-dose vial containing 900 mg/3 mL of rilpivirine extended-release injectable suspension

CABENUVA 400-mg/600-mg (2-mL) kit

- For use in once-monthly continuation injections only
- One single-dose vial containing 400 mg/2 mL of cabotegravir extended-release injectable suspension
- One single-dose vial containing 600 mg/2 mL of rilpivirine extended-release injectable suspension

Each dosing kit also contains 2 syringes, 2 syringe labels, 2 vial adapters, and 2 needles for IM injections (23 gauge, 1½ inch).

Storage

- Store CABENUVA in the refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton until ready to use
- Once the vials are removed from the refrigerator, they must be used or discarded. They cannot be cycled into and out of the refrigerator

- Do not freeze or mix with any other product or diluent

IM=intramuscular.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions, including Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported with CABENUVA or its components. 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

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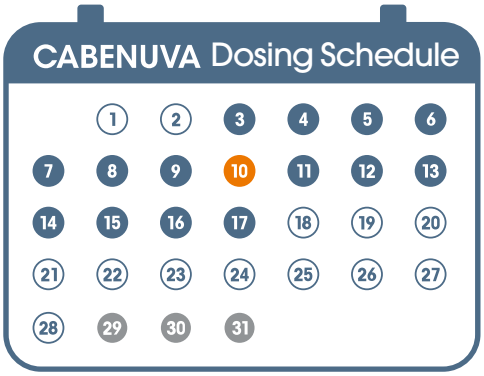
Setting a Target Treatment Date

Before initiation of CABENUVA, ensure that patients agree to the required every-2-month or once-monthly dosing schedule, and counsel patients about the importance of adherence to scheduled dosing visits

- It is important that patients set a consistent **Target Treatment Date** for their injections
- It is recommended that patients pick a day **between the 1st and the 28th** of a month and adhere to scheduled appointments for that date every 2 months or once monthly



- Target Treatment Date
- Dosing window (7 days before or 7 days after the Target Treatment Date)
- Not recommended for the Target Treatment Date due to varying number of days in each month

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity Reactions (cont'd):

- 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

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

Setting a Target Treatment Date (cont'd)

CABENUVA has dosing flexibility, allowing for injections to be given up to 7 days before or 7 days after the Target Treatment Date

- If patients receive their injections within the dosing window (up to 7 days before or 7 days after their Target Treatment Date) but not on the Target Treatment Date, the following dose should be scheduled for the original Target Treatment Date
- If a patient plans to miss a scheduled injection visit by more than 7 days, any fully suppressive antiretroviral regimen may be used until injections are resumed. Alternatively, oral cabotegravir and rilpivirine may be used for up to 2 months to replace 1 missed scheduled every-2-month injection visit. For more information on what to do if a patient misses an injection visit, see pages 8, 9, 12, and 13
- Patients who miss a scheduled injection visit should be clinically reassessed to ensure resumption of therapy remains appropriate

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

Please see additional Important Safety Information for CABENUVA throughout.
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CABENUVA
cabotegravir 200 mg/mL; rilpivirine 300 mg/mL
extended-release injectable suspensions

Starting every-2-month CABENUVA

Every-2-month dosing schedule

<table>
<tr><th colspan="2">Initiation</th><th></th><th>Continuation</th></tr>
<tr><td> 
Month 1</td><td> 
Month 2</td><td>Month 3</td><td> 
Months 4, 6, and beyond</td></tr>
<tr><td colspan="2">Administer the first 2 injections: cabotegravir 600 mg/3 mL and rilpivirine 900 mg/3 mL.

Administer the second set of initiation injections 1 month later.</td><td></td><td>For duration of treatment, administer injections: cabotegravir 600 mg/3 mL and rilpivirine 900 mg/3 mL every 2 months.</td></tr>
<tr><td colspan="4">2 IM injections at separate gluteal sites (opposite sides or at least 2 cm apart) during same visit</td></tr>
</table>

- An optional oral lead-in can be used to assess tolerability with CABENUVA
  - Prescribe cabotegravir and rilpivirine oral tablets, both taken once daily with a meal for approximately 1 month (at least 28 days). Initiation injections (cabotegravir 600 mg/3 mL and rilpivirine 900 mg/3 mL) should be administered on the last day of the optional oral lead-in
- Ensure you select the appropriate dosing kit prior to preparation
- Adherence to the every-2-month dosing schedule is strongly recommended. Setting a consistent injection date, the Target Treatment Date, can help keep your patients on track
- If injection dosing will be continued after a patient misses an injection visit, see pages 8 and 9 for detailed dosing recommendations on reinitiating CABENUVA after missed injections

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

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Switching from once-monthly to every-2-month dosing

Recommendations when switching from once-monthly to every-2-month dosing of CABENUVA

Continuation	Continuation		
1 month prior to switch	Month 1	Month 2	Months 3, 5, and beyond
Once-monthly continuation injections: Administer once-monthly CABENUVA continuation injections: cabotegravir **400 mg/2 mL** and rilpivirine **600 mg/2 mL** 1 month prior to starting every-2-month injections	**Every-2-month continuation injections:** Administer every-2-month CABENUVA injections: cabotegravir **600 mg/3 mL** and rilpivirine **900 mg/3 mL** 1 month after the continuation injection and continue every 2 months thereafter		
2 IM injections at separate gluteal sites (opposite sides or at least 2 cm apart) during same visit			

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, suicide 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

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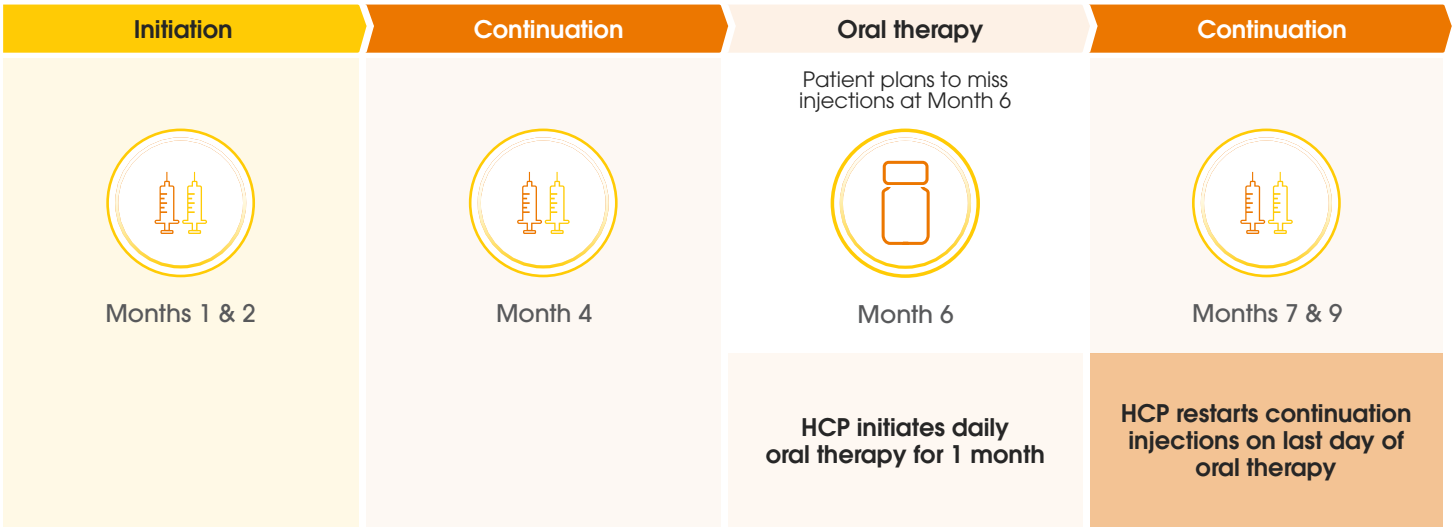
cabotegravir 200 mg/mL; rilpivirine 300 mg/mL
extended-release injectable suspensions

Planned missed injections

For planned missed injections, consider oral therapy with cabotegravir and rilpivirine

- If a patient plans to miss a scheduled injection visit by more than 7 days:
  - Any fully suppressive oral antiretroviral regimen may be used to cover a planned missed injection visit
  - Oral cabotegravir (30-mg tablet) in combination with rilpivirine (25-mg tablet) once daily may be used for up to 2 consecutive months to cover a planned missed injection visit
- The first dose of oral therapy should be taken approximately 2 months after the last injection dose of CABENUVA and continued until the day injection dosing is restarted

Hypothetical treatment plan if a patient plans to miss their injections



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

Please see additional Important Safety Information for CABENUVA throughout.
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CABENUVA
cabotegravir 200 mg/mL; rilpivirine 300 mg/mL
extended-release injectable suspensions

Continuing after missed injections

Before initiation of CABENUVA, ensure that patients agree to the required every-2-month dosing schedule, and counsel patients about the importance of adherence to scheduled dosing visits

Continuing after **planned** missed injections

Your patient is restarting injections after planned missed injections.

How much time has passed since their missed Target Treatment Date?

≤1 month since missed Target Treatment Date

Resume injections on final day of oral therapy. Continue with every-2-month dosing schedule thereafter.

>1 month since missed Target Treatment Date

Repeat initiation injections on final day of oral therapy 1 month apart for 2 consecutive months. Continue every-2-month dosing schedule thereafter.

Continuing after **unplanned** missed injections

Adherence to scheduled injection visits is important. Your patient missed the Target Treatment Date by >7 days and did not plan for it by taking oral therapy.

Clinically reassess the patient to determine whether long-acting treatment remains appropriate.

How much time has passed since their missed Target Treatment Date?

≤1 month since missed Target Treatment Date

Resume injections as soon as possible. Continue with every-2-month dosing schedule thereafter.

>1 month since missed Target Treatment Date

Repeat initiation injections as soon as possible 1 month apart for 2 consecutive months. Continue every-2-month dosing schedule thereafter.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

- The most common adverse reactions (incidence ≥2%, Grades 1 to 4) with CABENUVA were injection site reactions, pyrexia, fatigue, headache, musculoskeletal pain, nausea, sleep disorders, dizziness, and rash

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extended-release injectable suspensions

Starting once-monthly CABENUVA

Once-monthly dosing schedule

Initiation	Continuation
 **Month 1**	 **Months 2 and beyond**
Administer the first CABENUVA injections (1 LA cabotegravir **600 mg/3 mL** and 1 LA rilpivirine **900 mg/3 mL**).	For duration of treatment, administer CABENUVA injections monthly (1 LA cabotegravir **400 mg/2 mL** and 1 LA rilpivirine **600 mg/2 mL**).
2 IM injections at separate sites (opposite sides or 2 cm apart) during same visit	

LA=long-acting.

- An optional oral lead-in can be used to assess tolerability with CABENUVA
  - Prescribe cabotegravir and rilpivirine oral tablets, both taken once daily with a meal for approximately 1 month (at least 28 days). Initiation injections (cabotegravir 600 mg/3 mL and rilpivirine 900 mg/3 mL) should be administered on the last day of the optional oral lead-in
- Ensure you select the appropriate dosing kit prior to preparation
- Adherence to the once-monthly injection dosing schedule is strongly recommended. Setting a consistent injection date, the Target Treatment Date, can help keep your patients on track
- If injection dosing will be continued after a patient misses an injection visit, see pages 12 and 13 for detailed dosing recommendations on reinitiating CABENUVA after missed injections

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

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Switching from every-2-month to once-monthly dosing

Recommendations when switching from every-2-month to once-monthly dosing of CABENUVA

Continuation	Continuation	
		
2 months prior	**Month 1**	**Months 2 and beyond**
Every-2-month continuation injections Administer every-2-month CABENUVA injections (1 LA cabotegravir **600 mg/3 mL** and 1 LA rilpivirine **900 mg/3 mL**) 2 months prior to starting once-monthly injections.	**Once-monthly continuation injections** Administer once-monthly CABENUVA injections (1 LA cabotegravir **400 mg/2 mL** and 1 LA rilpivirine **600 mg/2 mL**) 2 months after the last continuation injections and continue once-monthly thereafter.	
2 IM injections at separate gluteal sites (opposite sides or 2 cm apart) during same visit		

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:** Potential risks of breastfeeding include HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant

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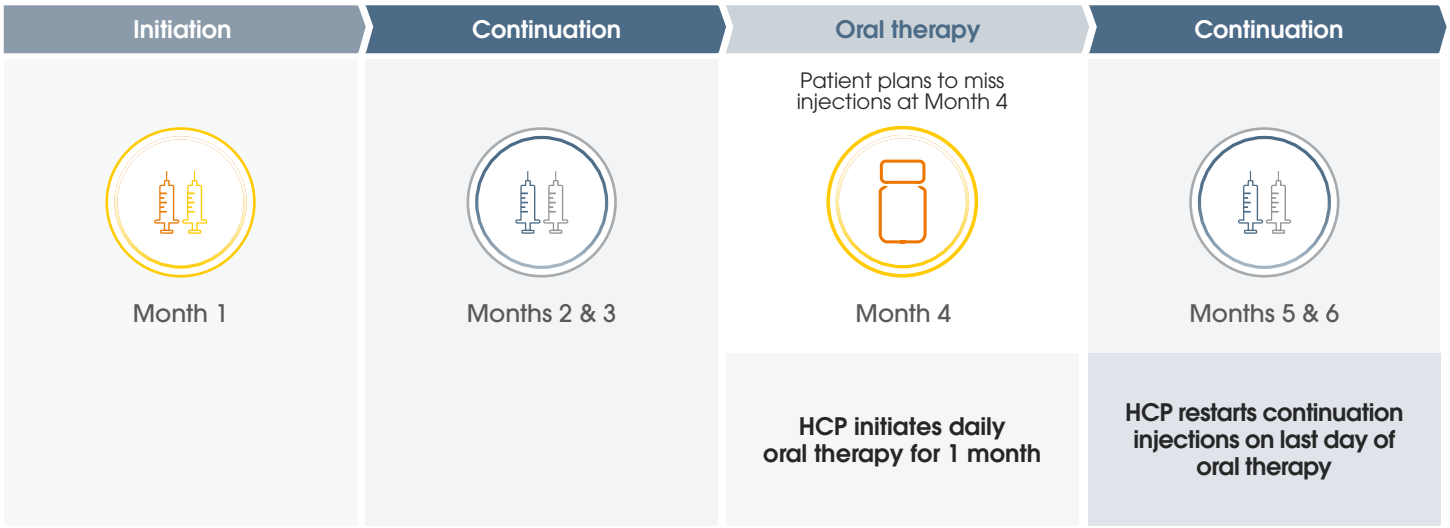
Planned missed injections

For planned missed injections, consider oral therapy with cabotegravir and rilpivirine

- If a patient plans to miss a scheduled injection visit by more than 7 days:
  - Any fully suppressive oral antiretroviral regimen may be used to cover a planned missed injection visit
  - Oral cabotegravir (30-mg tablet) in combination with rilpivirine (25-mg tablet) once daily may be used for up to 2 consecutive months to cover a planned missed injection visit
- The first dose of oral therapy should be taken 1 month (+/- 7 days) after the last injection dose of CABENUVA and continued until the day injection dosing is restarted

Hypothetical treatment plan if a patient plans to miss their injections



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

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Continuing after missed injections

Before initiation of CABENUVA, ensure that patients agree to the required once-monthly dosing schedule, and counsel patients about the importance of adherence to scheduled dosing visits

Continuing after **planned** missed injections

Your patient is restarting injections after planned missed injections

How much time has passed since their missed Target Treatment Date?

≤1 month since missed Target Treatment Date

Resume injections on final day of oral therapy. Continue with once-monthly dosing schedule thereafter.

>1 month since missed Target Treatment Date

Repeat initiation injections on final day of oral therapy. Continue once-monthly dosing schedule thereafter.

Continuing after **unplanned** missed injections

Adherence to scheduled dosing visits is important. Your patient missed their Target Treatment Date by >7 days and did not plan for it by taking oral therapy.

Clinically reassess the patient to determine whether long-acting treatment remains appropriate.

How much time has passed since their missed Target Treatment Date?

≤1 month since missed Target Treatment Date

Resume injections as soon as possible. Continue with once-monthly dosing schedule thereafter.

>1 month since missed Target Treatment Date

Repeat initiation injections as soon as possible. Continue once-monthly dosing schedule thereafter.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions:

- Serious or severe hypersensitivity reactions, including Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported with CABENUVA or its components. 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

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Pre-injection considerations

Tips for your patients

Communicate

- Let patients know what to expect with injections
- Counsel patients about the importance of adherence to scheduled dosing visits
- Allow enough time to address patients' questions

Empower

- Include patients in decision-making about the timing of injections and their preferred position for injections

Encourage relaxation

- Give patients time to relax prior to injections
- Deep breathing, music, or distractions can help
- Ensure patients relax the gluteal muscle prior to injections

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Hypersensitivity Reactions (cont'd):

- 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

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Pre-injection overview

Preparation overview

- A complete dose of CABENUVA requires 1 dose each of cabotegravir and rilpivirine
- Cabotegravir and rilpivirine are suspensions that do not need further dilution or reconstitution
- The preparation steps for both medicines are the same. Carefully follow these instructions when preparing the suspension for injection to avoid leakage
- Cabotegravir and rilpivirine are for gluteal IM use only. Each injection must be administered to separate gluteal sites (on opposite sides or at least 2 cm apart)
  - The ventrogluteal site is recommended for injections. **The administration order is not important**
- Before initiation of CABENUVA, ensure that patients agree to the required dosing schedule, and counsel patients about the importance of adherence to scheduled dosing visits

Prior to administration

- It is recommended to label the syringe with the time that the medication has been drawn into the syringe if the medication is not administered immediately
- See FAQs on page 20 for other considerations prior to administration

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

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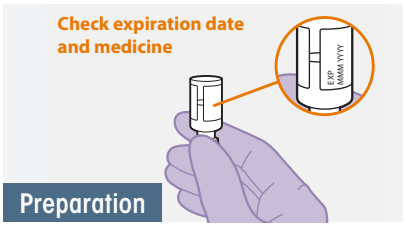
Instructions for use: preparation

Ensure you select the appropriate dosing kit prior to preparation[1]

CABENUVA 600-mg/900-mg (3-mL) kit

CABENUVA 400-mg/600-mg (2-mL) kit

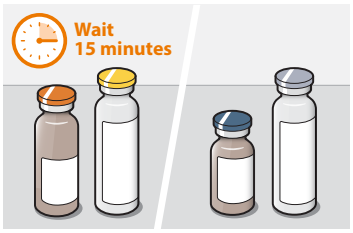
1 Inspect both vials



- Check that the expiration date has not passed
- Inspect the vials immediately. If you can see foreign matter, do not use the product

Note: The cabotegravir vial has a brown tint to the glass.
Do not use if the expiration date has passed.

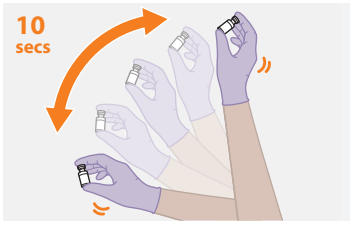
2 Wait 15 minutes



- Wait at least 15 minutes before you are ready to give the injection to allow the medication to come to room temperature

Note: Orange and yellow vials represent the 600-mg/900-mg (3-mL) kit, and blue and gray vials represent the 400-mg/600-mg (2-mL) kit.

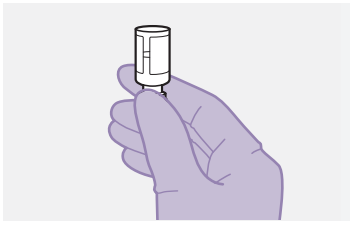
3 Shake the vial vigorously



- Hold the vial firmly, and vigorously shake for a full 10 seconds

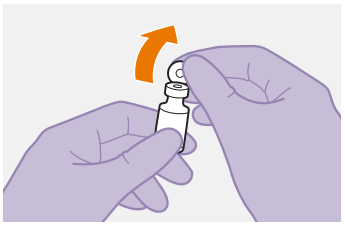
Note: Vial preparation order is not important.

4 Inspect suspension



- Invert the vial and confirm the suspension is uniform. It should look uniform
- If the suspension is not uniform, shake the vial again
- It is also normal to see small air bubbles

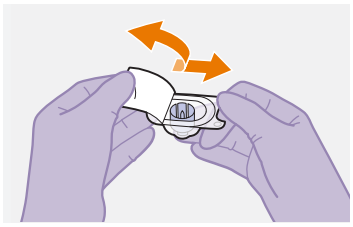
5 Remove the vial cap



- Remove the cap from the vial
- Wipe the rubber stopper with an alcohol wipe

Do not allow anything to touch the rubber stopper after wiping it.

6 Peel open the vial adapter



- Peel off the paper backing from the vial adapter packaging

Note: Do not remove the adapter from its packaging for the next step. The adapter **will not** fall out when its packaging is turned upside down.

Please see accompanying full Prescribing Information, including Instructions for Use, for CABENUVA.

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

Instructions for use: preparation (cont'd)

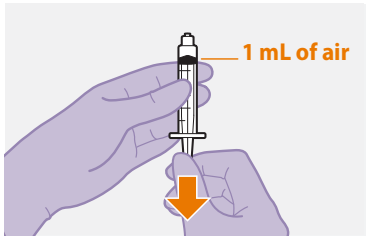
7 Place vial on flat surface and attach the vial adapter

- Ensure the vial is upright and on a flat surface
- Press the vial adapter straight down onto the vial, as shown
- The vial adapter should click securely into place

8 Lift off the packaging

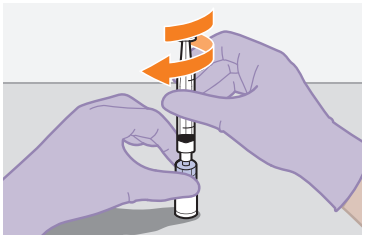
- Lift off the vial adapter packaging, as shown

9 Prepare the syringe



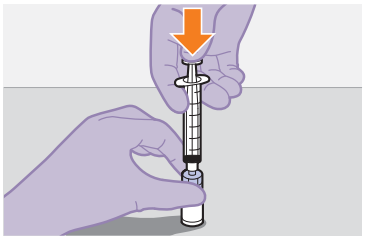
- Remove the syringe from its packaging
- Draw 1 mL of air into the syringe. This will make it easier to draw up the medicine later

10 Attach the syringe



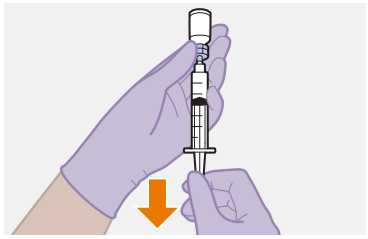
- Hold the vial adapter and vial firmly, as shown
- Screw the syringe firmly onto the vial adapter

11 Press the plunger



- Press the plunger all the way down to push the air into the vial

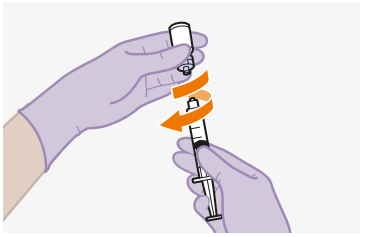
12 Slowly draw up the dose



- Invert the syringe and vial, and slowly withdraw as much of the medicine as possible into the syringe. There may be more medicine than the dose amount

Note: Keep the syringe upright to avoid leakage.

13 Unscrew the syringe



- Hold the syringe plunger firmly in place as shown to prevent leakage. It is normal to feel some back pressure
- Unscrew the syringe from the vial adapter, holding the vial adapter as shown

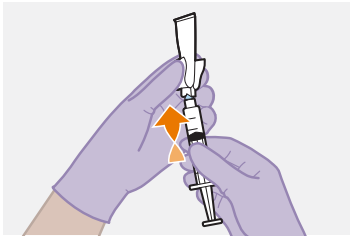
Note: Check that the suspension looks uniform and milky white.

Please see accompanying full Prescribing Information, including Instructions for Use, for CABENUVA.

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

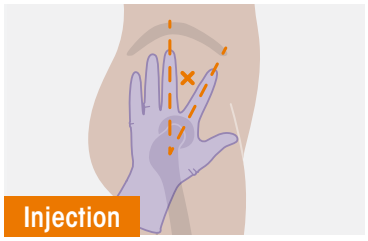
Instructions for use: injection

14 Attach the needle and affix syringe label



- Peel open the needle packaging partway to expose the needle base
- Keeping the syringe upright, firmly twist the syringe onto the needle
- Remove the needle packaging from the needle
- Write the name of the medicine on the syringe label. Affix the label to the syringe, making sure the gradations remain visible

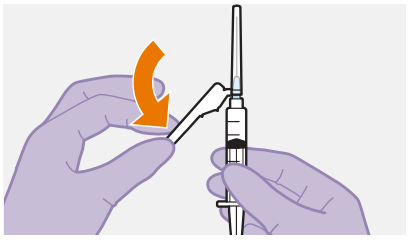
15 Prepare the injection site



- Injections must be administered to a gluteal site
- Select from the following areas for the injection:
  - Ventrogluteal, as shown (recommended)
  - Dorsogluteal, not shown (upper outer quadrant)

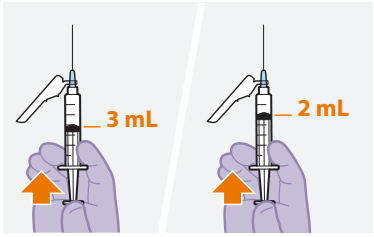
Note: For gluteal intramuscular use only.
Do not inject intravenously.

16 Remove the cap



- Fold the needle guard away from the needle
- Pull off the injection needle cap

17 Remove extra liquid from the syringe

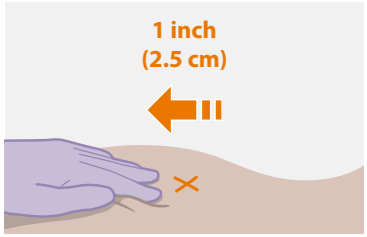


- Hold the syringe with the needle pointing up
- Press the plunger to the appropriate volume to remove extra liquid and any air bubbles

Note: Clean the injection site with an alcohol wipe. Allow the skin to air-dry before continuing.

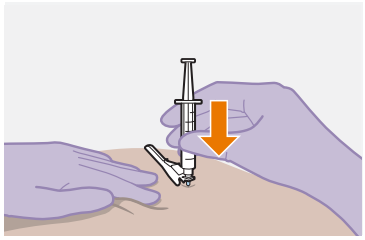
Note: 3 mL represents the 600-mg/900-mg doses and 2 mL represents the 400-mg/600-mg doses.

18 Stretch the skin



- Use the Z-track injection technique to minimize medicine leakage from the injection site
- Firmly drag the skin covering the injection site, displacing it by about an inch (2.5 cm)
- Keep it held in this position for the injection

19 Insert the needle



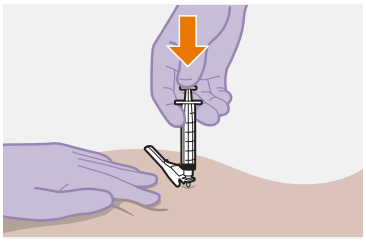
- Insert the needle to its full depth, or deep enough to reach the muscle

Please see accompanying full Prescribing Information, including Instructions for Use, for CABENUVA.

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

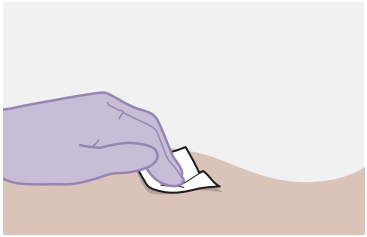
Instructions for use: injection (cont'd)

20 Inject the dose of medicine



- Still holding the skin stretched—slowly press the plunger all the way down
- Ensure the syringe is empty
- Withdraw the needle and release the stretched skin immediately

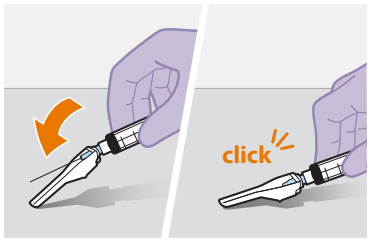
21 Assess the injection site



- Apply pressure to the injection site using a gauze pad
- A small bandage may be used if bleeding occurs

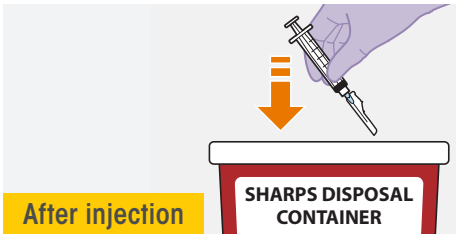
Do not massage the area.

22 Make the needle safe



- Fold the needle guard over the needle
- Gently apply pressure using a hard surface to lock the needle guard in place
- The needle guard will make a click when it locks

23 Dispose safely



- Dispose of used needles, syringes, vials, and vial adapters according to local health and safety laws

Repeat for 2nd medicine

- If you have not yet injected both medicines, use the same steps for preparation and injection of the other medicine
- The second medicine must be injected into a separate gluteal intramuscular site (on opposite sides or at least 2 cm apart)

Observe patients for approximately 10 minutes after the injections.

Please see accompanying full Prescribing Information, including Instructions for Use, for CABENUVA.

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

Frequently asked questions

1 How long can the medicines be left out of the refrigerator?

- It is best to inject the medicines as soon as they reach room temperature. However, the vials may sit in the carton at room temperature (maximum temperature of 25°C [77°F]) for up to 6 hours. Do not put back into the refrigerator
- If not used within 6 hours, the medicines must be discarded

Note: Once the vials are removed from the refrigerator, they must be used or discarded. They cannot be cycled in and out of the refrigerator.

2 How long can the medicines be left in the syringes?

- It is best to inject the (room-temperature) medicines as soon as possible after drawing them up. However, the medications can remain in the syringes for up to 2 hours before injecting
- The filled syringes should not be placed in the refrigerator. If 2 hours are exceeded, the filled syringes and needles must be discarded

3 Why do I need to inject air into the vials?

- Injecting 1 mL of air into the vials makes it easier to draw up the medicines into the syringes. Without the air, some liquid may flow back into the vials unintentionally, leaving less medicine than intended in the syringes

4 Does the order in which I give the medicines matter?

- No, the order is unimportant

5 Is it safe to warm the vials up to room temperature more quickly?

- It is best to let the vials come to room temperature naturally. However, you can use the warmth of your hands to speed up the warm-up time, but make sure the vials do not get above 25°C (77°F)
- Do not use any other heating methods

Please see accompanying full Prescribing Information, including Instructions for Use, for CABENUVA.

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

Learn more about the dosing and administration of CABENUVA by visiting **CABENUVAhcp.com**

Reference:

1. Data on file. ViiV Healthcare group of companies. Durham, NC.

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