CABENUVA

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. What is CABENUVA and what is it used for?

CABENUVA contains the active ingredients cabotegravir and rilpivirine. CABENUVA is used to treat Human Immunodeficiency Virus (HIV) infection in adults aged 18 years and over.

For more information, see Section 1. What is CABENUVA and what is it used for? in the full CMI.

2. What should I know before I am given CABENUVA?

Do not use CABENUVA if you have ever had an allergic reaction to cabotegravir, rilpivirine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given CABENUVA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CABENUVA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is CABENUVA given?

- You will be given CABENUVA as two injections, once every month or once every two months. A nurse or doctor will give you the injections in the muscle on each side of your buttocks (intramuscular injection [IM]).
- You should continue receiving CABENUVA for as long as your doctor recommends. Do not stop unless your doctor advises you.

More instructions can be found in Section 4. How is CABENUVA given? in the full CMI.

5. What should I know while being given CABENUVA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using CABENUVA. • Attend your planned appointments to have CABENUVA injections, have regular blood tests and stay in regular contact with your doctor. • Continue to protect people as CABENUVA may stop you passing HIV infection on to others.
Things you should not do	• Do not stop using CABENUVA without talking to your doctor. • Do not take CABENUVA with certain medicines that treat bacterial infections or anticonvulsants, or products containing St John's wort.
Driving or using machines	• CABENUVA injections can make you dizzy and have other side effects that make you less alert. • Do not drive or use machines unless you are sure you are not affected.
Looking after your medicine	• Keep your injections in the pack until it is time to receive them. • Keep your injections in a refrigerator at 2°C- 8°C. Do not freeze.

For more information, see Section 5. What should I know while being given CABENUVA? in the full CMI.

6. Are there any side effects?

The following common side effects may occur when using CABENUVA: headache, injection site reactions, feeling hot, depression, anxiety, abnormal dreams, insomnia, dizziness, nausea, vomiting, stomach pain, diarrhoea, rash, muscle, chest or back pain and fatigue. Contact your doctor promptly if you develop an allergic reaction or have liver problems.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

CABENUVA

Active ingredients: *cabotegravir prolonged-release suspension for injection and rilpivirine prolonged-release suspension for injection*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CABENUVA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CABENUVA.**

Where to find information in this leaflet:

1. What is CABENUVA and what is it used for?
2. What should I know before I am given CABENUVA?
3. What if I am taking other medicines?
4. How CABENUVA is given?
5. What should I know while being given CABENUVA?
6. Are there any side effects?
7. Product details

1. What is CABENUVA and what is it used for?

CABENUVA contains two medicines, cabotegravir prolonged-release suspension for injection and rilpivirine prolonged-release suspension for injection, packaged together. Cabotegravir belongs to a group of anti-retroviral medicines called integrase inhibitors (INIs) and rilpivirine belongs to a group of antiretroviral medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs).

CABENUVA is used to treat Human Immunodeficiency Virus (HIV) infection in adults aged 18 years and over.

CABENUVA does not cure HIV infection; it keeps the amount of virus in your body at a low level. This helps maintain the number of CD4+ cells in your blood. CD4+ cells are a type of white blood cell that are important in helping your body to fight infection.

CABENUVA will replace your current antiretroviral treatment. To control your HIV infection, you must attend your planned appointments to receive CABENUVA, unless your doctor tells you to stop. If you stop CABENUVA, it is important to see your doctor who will give you other antiretroviral medicines to treat your HIV infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is not enough information to recommend the use of this medicine for children and adolescents under the age of 18 years.

2. What should I know before I am given CABENUVA?

Regular appointments are important
It is important that you **attend your planned appointments** to receive your CABENUVA injections, to control your HIV infection, and to stop your illness from getting worse. Talk to your doctor if you are thinking about stopping treatment. If you are late receiving your CABENUVA injections, or if you stop receiving CABENUVA, you will need to take other medicines to treat HIV infection and to reduce the risk of developing viral resistance.

CABENUVA is a long-acting medication. If you stop treatment, low levels of cabotegravir and rilpivirine (the active ingredients of CABENUVA) can remain in your system for up to 12 months or more and 4 years, respectively, after your last injections. These low levels of medicine could cause interactions with other medicines and will not protect you against the virus and the virus may become resistant. You must start a different HIV treatment within one month of your last CABENUVA injections if you are having monthly injections, and within two months of your last CABENUVA injections if you are having injections every two months

Warnings

You must not be given CABENUVA if:

- you are allergic to cabotegravir or rilpivirine or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- if you are taking rifampicin or rifapentine (to treat some bacterial infections such as tuberculosis) or phenytoin, phenobarbital, carbamazepine or oxcarbazepine (anticonvulsants used to treat epilepsy and prevent seizures) or medicines containing St. John's wort (hypericum perforatum), a herbal product used to treat depression.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions, such as kidney or liver problems. **Your liver function will be monitored by your doctor during treatment with CABENUVA.**
- take any medicines for any other condition.

Symptoms of infection and inflammation:

People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). When they start treatment, the immune system becomes stronger, so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up again as the body fights them
- the immune system attacking healthy body tissue (autoimmune disorders).

The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection.

Symptoms may include:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands feet and moving towards the trunk of the body
- palpitations or tremor
- hyperactivity (excessive restlessness and movement).

If you get any symptoms of infection or if you notice any of the symptoms above tell your doctor immediately. Don't take other medicines for the infection without your doctors' advice.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor can discuss with you the risks and benefits, to you and your baby, of receiving CABENUVA injections while pregnant.

If you are planning to have a baby, talk to your doctor in advance, as the injections in CABENUVA can stay in your system for up to 12 months or longer after the last injections.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Where possible, women who are HIV-positive should not breastfeed, because HIV infection can be passed on to the baby in breast milk.

It is not known whether the ingredients in the CABENUVA injections can pass into breast milk and harm your baby. They may still pass into breast milk for 12 months after the last injections.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and the CABENUVA injections may interfere with each other. These include:

- carbamazepine, oxcarbazepine, phenobarbital, or phenytoin (also known as anticonvulsants used to treat epilepsy and prevent seizures)
- rifabutin, rifampicin or rifapentine (to treat some bacterial infections such as tuberculosis)
- clarithromycin and erythromycin (antibiotics used to treat bacterial infections)
- methadone (a medicine used for pain)
- dexamethasone (a corticosteroid used in a variety of conditions such as inflammation and allergic reactions)
- products containing St. John's wort (hypericum perforatum), a herbal product used to treat depression.
- medicines for the treatment of hepatitis C.

These medicines may be affected by CABENUVA injections or may affect how well they work. You may need different amounts of your medicines, or you may need to take different medicines

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CABENUVA.

4. How is CABENUVA given?

How much is given

- When you first start treatment with CABENUVA, you and your doctor may decide to start directly with CABENUVA injections.
- Alternatively, your doctor may advise you to take VOCABRIA (cabotegravir) tablets (30 mg) and rilpivirine tablets (25 mg), once a day, for one month (lead-in period) before your first CABENUVA injections. Taking VOCABRIA tablets and rilpivirine tablets before you receive CABENUVA injections will allow your doctor to test how well you tolerate these medicines.
- In the second month (following 1 month oral treatment) you will receive CABENUVA 3 mL injections (cabotegravir 600 mg in 3 mL injection and rilpivirine 900 mg in 3 mL injection) at the same visit.
- Following this, you will be given CABENUVA as two injections, either once every month or once every 2 months. Your doctor will advise you of your dosing schedule.

How CABENUVA is given

- You will be given CABENUVA as two injections, once every month or once every two months.
- A nurse or doctor will give you the injections in the muscle on each side of your buttocks (intramuscular injection [IM]).

How long should CABENUVA be given for

Continue receiving your medicine for as long as your doctor tells you.

CABENUVA injections are prolonged-release medications, so if you stop treatment, the injections will remain in your system for up to a year or more after your last injection.

It is important that you attend your planned appointments to receive your CABENUVA injections.

If you miss your CABENUVA injections

If you miss an appointment to receive your injections, contact your doctor right away to make a new appointment.

Talk to your doctor if you think you will not be able to receive your CABENUVA injections at the usual time. Your doctor may recommend you take VOCABRIA and rilpivirine tablets instead, until you are able to receive your CABENUVA injections again.

Talk to your doctor if you are thinking about stopping treatment. You will need to take other medicines to treat your HIV infection and prevent development of viral resistance if you are late receiving or stop receiving CABENUVA injections.

These medicines help to control your condition but do not cure it. It is important to keep receiving your medicines even if you feel well.

If you are given too much CABENUVA

A doctor or nurse will give these injections to you, so it is unlikely that you will be given too much. If you are worried, talk to the doctor or nurse.

5. What should I know while being given CABENUVA?

Things you should do

- **Have regular blood tests**

For as long as you're receiving CABENUVA, your doctor will arrange regular blood tests to check for side effects.

- **Stay in regular contact with your doctor**

CABENUVA helps to control your condition, but it is not a cure for HIV infection. Your need to receive CABENUVA injections once every month or once every 2 months (depending on your dosing schedule) to stop your illness getting worse. Because CABENUVA does not cure HIV infection, you may still develop other infections or illnesses linked to HIV infection.

Keep in contact with your doctor and attend your planned appointments to receive CABENUVA injections. Don't stop without your doctor's advice.

- **Protect other people**

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). CABENUVA will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:

  - Use a condom when you have oral or penetrative sex.
  - Don't risk blood transfer - for example, don't share needles

Call your doctor straight away if you:

- If you become pregnant while receiving CABENUVA.

Remind any doctor, dentist or pharmacist you visit that you are using CABENUVA.

Things you should not do

- Do not pass on your medicine to anyone else. It may harm them even if they have the same condition as you.
- Do not stop your medicine without talking to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CABENUVA affects you.

These injections may cause dizziness, in some people or other side effects that make you less alert.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- Keep your injections in the pack until it is time to receive them.
- Keep your injections in a refrigerator at 2°C to 8°C. Do not freeze.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of the CABENUVA injections or other medicines you are taking, or an effect of the HIV disease itself. It is very important to talk to your doctor about any changes in your health.

Some side effects may only be seen in your blood tests and may not appear immediately after you start receiving CABENUVA injections. If you get any of these side effects, and if they are severe, your doctor may advise you to stop CABENUVA injections.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection site reactions: *Very common** • Pain & tenderness, a hardened mass or lump *Common*** • Redness, itching, swelling, warmth, numbness or bruising (which may include discolouration or a collection of blood under the skin) *Uncommon**** • An abscess (collection of pus) **Nervous system and psychiatric disorders:** *Very common* • Headache *Common* • Dizziness • Depression (feelings of deep sadness and unworthiness) • Anxiety • Abnormal dreams • Difficulty in sleeping (insomnia) *Uncommon* • Feeling drowsy (somnolence) **Gastrointestinal disorders:** *Common* • Diarrhoea • Feeling sick (nausea) • Being sick (vomiting) • Stomach (abdominal) pain or discomfort • Wind (flatulence) **General disorders:** *Very common* • Feeling hot (pyrexia), which may occur within one week after injections *Common* • Lack of energy (fatigue) • Feeling weak (asthenia) • Generally feeling unwell (malaise) **Other:** *Common* • Rash • Muscle pain (myalgia) • Pain (e.g. back and chest) *Uncommon* • Weight gain	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
Side effects that may show up in blood tests: • increase in bilirubin (a substance produced by the liver) in the blood • an increase in lipase (an enzyme produced by the pancreas). • an increase in the level of enzymes produced in the muscles (creatine phosphokinase, creatinine)	

*Very common: may affect more than 1 in 10 people

** Common: may affect up to 1 in 10 people

***Uncommon: may affect up to 1 in 100 people

Serious side effects

Serious side effects	What to do
Allergic reactions: • Rash, itching or hives on skin • High temperature (fever) • Lack of energy (fatigue) • Swelling of the face, lips, tongue or other parts of the body • Wheezing or difficulty breathing • Shortness of breath • Muscle or joint aches **Liver disorders:** *Uncommon**** • Changes in liver blood tests (increase in transaminases) • Liver damage (signs may include yellowing of the skin and the whites of the eyes, loss of appetite, itching, tenderness of the stomach, light-coloured stools or unusually dark urine). (hepatotoxicity)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CABENUVA contains

Active ingredient (main ingredient)	**CABENUVA 2 mL** • cabotegravir 400 mg • rilpivirine 600 mg **CABENUVA 3 mL** • cabotegravir 600 mg • rilpivirine 900 mg
Other ingredients (inactive ingredients)	**Cabotegravir injections:** • mannitol • polysorbate 20 • macrogol 3350 • water for injections **Rilpivirine injections:** • citric acid monohydrate • glucose monohydrate • poloxamer • sodium phosphate monohydrate • sodium hydroxide • water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What CABENUVA looks like

CABENUVA 2 mL

Each carton contains the following components:

- 1 vial of 2 mL cabotegravir prolonged-release suspension for injection which is a white to light pink suspension.
- 1 vial of 2 mL rilpivirine prolonged-release suspension for injection which is a white to off-white suspension
- 2 vial adaptors
- 2 syringes
- 2 needles (23 gauge, 1½ inch)

CABENUVA 3 mL

Each carton contains the following components:

- 1 vial of 3 mL cabotegravir prolonged-release suspension for injection which is a white to light pink suspension.
- 1 vial of 3 mL rilpivirine prolonged-release suspension for injection which is a white to off-white suspension
- 2 vial adaptors
- 2 syringes
- 2 needles (23 gauge, 1½ inch)

AUST R 323783 & 323784.

Who distributes CABENUVA

ViiV Healthcare Pty Ltd

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Australia

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