



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

cabotegravir prolonged-release suspension for injection; rilpivirine prolonged-release suspension for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CABENUVA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving CABENUVA against the benefits they expect it will have for you.

If you have any concerns about receiving this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CABENUVA is used for

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

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 nonnucleoside

reverse transcriptase inhibitors (NNRTIs).

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 cells 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.

Before you are 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 injection 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 injection. 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.

When you must not receive it

You must not be given CABENUVA injections if you have an allergy to:

- any medicine containing cabotegravir or rilpivirine
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- a 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 pain

You must not be given CABENUVA injections if you are taking any of these medicines:

- rifabutin, rifampicin or rifapentine (to treat some bacterial infections such as tuberculosis)
- phenytoin, phenobarbital, carbamazepine or oxcarbazepine (also known as anticonvulsants used to treat epilepsy and prevent seizures)
- products containing St. John's wort (*hypericum perforatum*), a herbal product used to treat depressions.

You must not be given CABENUVA injections after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you start to receive it

Some other conditions may develop during HIV treatment.

Tell your doctor or pharmacist if you experience severe or troublesome reactions at the site where you are given your injections.

- **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 a 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.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems.
- liver problems.

Signs of liver problems include yellowing of the skin and the whites of eyes, loss of appetite, itching tenderness of the stomach, light coloured stools or unusually dark urine

Your liver function will be monitored by your doctor during treatment with CABENUVA.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. 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.

Where possible, women who are HIV-positive should not breast feed, 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.

If you have not told your doctor about any of the above, tell him/her before you start receiving CABENUVA injections.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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 depressions.
- 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving this medicine.

How CABENUVA is given

How much is given

When you first start treatment with CABENUVA, your doctor will 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 it 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 of each side

of your buttocks (intramuscular injection [IM]).

How long it should be given

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 a dose or stop treatment

Take CABENUVA for as long as your doctor recommends. Don't stop unless your doctor advises you to. 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 does not cure it. It is important to keep receiving your medicines even if you feel well.

If you are given too much (overdose)

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.

While you are receiving CABENUVA

Things you must do

- You will need 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. You need to receive CABENUVA injections every 8 weeks to stop your illness from 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 injections 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 (e.g. don't share needles)

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving CABENUVA injections.

Tell any other doctors, dentists, and pharmacists who treat you that you are receiving this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are receiving this medicine.

It may affect other medicines used during surgery.

If you become pregnant while receiving this medicine, tell your doctor immediately.

Things you must 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.

Things to be careful of

Do not drive or operate machinery until you know how CABENUVA injections 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving CABENUVA injections.

These medicines help most people with HIV, but they may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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 effects, and if they are severe, your doctor may advise you to stop CABENUVA injections.

As well as the effects listed below for CABENUVA injections, other conditions can develop during combination therapy for HIV.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

Very common side effects

These may affect more than 1 in 10 people:

- headache
- injection site reactions - in clinical studies, these were generally mild to moderate and became less frequent over time. Symptoms may include:
 - very common: pain and discomfort, a hardened mass or lump
 - common: redness, itching, swelling, warmth or bruising, (which may include discolouration or a collection of blood under the skin).
 - uncommon: numbness, minor bleeding, an abscess (collection of pus) or cellulitis (warmth, swelling or redness).
- feeling hot (pyrexia), which may occur within one week after injections.

Common side effects

These may affect up to 1 in 10 people:

- depression

- anxiety
- abnormal dreams
- difficulty sleeping (insomnia)
- dizziness
- feeling sick (nausea)
- vomiting
- stomach pain (abdominal pain)
- wind (flatulence)
- diarrhoea
- rash
- muscle pain (myalgia)
- lack of energy (fatigue)
- feeling weak (asthenia)
- generally feeling unwell (malaise)
- weight gain
- pain (eg. back and chest)

Uncommon side effects

These may affect up to 1 in 100 people:

- feeling drowsy (somnolence)
- liver damage
- changes in liver blood tests

Other side Effects that may show up in blood tests

Other side effects have occurred in some people but their exact frequency is unknown:

- 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)

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After receiving CABENUVA

Storage

Keep your injections in the pack until it is time to take them.

Keep your injections in a refrigerator at 2°C to 8°C. Do not freeze.

Keep it where children cannot reach it.

Disposal

If your doctor tells you to stop this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it 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 offwhite 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)

Ingredients

CABENUVA 2 mL

Active ingredients:

- cabotegravir 400 mg
- rilpivirine 600 mg

Cabotegravir injections contains the following other ingredients:

- mannitol
- polysorbate 20
- macrogol 3350
- water for injections

Rilpivirine injections contains the following other ingredients:

- citric acid monohydrate
- glucose monohydrate
- poloxamer
- sodium phosphate monohydrate
- sodium hydroxide
- water for injections

CABENUVA 3 mL

Active ingredients:

- cabotegravir 600 mg
- rilpivirine 900 mg

Cabotegravir injections contains the following other ingredients:

- mannitol
- polysorbate 20
- macrogol 3350
- water for injections

Rilpivirine injections contains the following other ingredients:

- citric acid monohydrate
- glucose monohydrate
- poloxamer
- sodium phosphate monohydrate
- sodium hydroxide
- water for injections

Supplier

CABENUVA is supplied in Australia by:

ViiV Healthcare Pty Ltd
Level 4, 436 Johnston Street
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AUST R 323783 & 323784.

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