
VOCABRIA 200 mg/mL
Prolonged-release suspension for injection
Patient Information Leaflet

SCHEDULING STATUS:

S4

VOCABRIA 400 mg (2 mL)

VOCABRIA 600 mg (3 mL)

Prolonged-release Suspension for Injection

Cabotegravir 200 mg/mL

Contains sugar (mannitol 35,0 mg/mL)

Read all this leaflet carefully before you are given VOCABRIA Injections.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet:

1. What VOCABRIA injection is and what it is used for
2. What you need to know before you are given VOCABRIA injection
3. How VOCABRIA injection is given
4. Possible side effects
5. How to store VOCABRIA injection
6. Contents of the pack and other information.

1. What VOCABRIA injection is and what it is used for:

VOCABRIA injections are used to treat HIV (human immunodeficiency virus) infection in adults.

VOCABRIA contains the active ingredient cabotegravir, which belongs to a group of antiretroviral medicines called *integrase inhibitors* (INIs).

VOCABRIA 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.

VOCABRIA injections are always given, in combination with another anti-retroviral medicine called rilpivirine injection to treat HIV infection. To control your HIV infection, and to stop your illness from getting worse, you must keep taking all your medicines, unless your doctor tells you to stop taking any.

2. What you need to know before you are given VOCABRIA injection:

VOCABRIA injection should not be administered to you:

- if you are allergic (hypersensitive) to cabotegravir or to any of the other ingredients of VOCABRIA (listed in section 6)
- if you are taking any of these medicines:
 - rifampicin or rifapentine (to treat some bacterial infections such as tuberculosis)
 - phenytoin, phenobarbitone, carbamazepine or oxcarbazepine (also known as anticonvulsants used to treat epilepsy and prevent seizures)

You should not receive a VOCABRIA injection if you are taking any of these medicines. Tell your doctor if you are taking any of the above medicines.

Warnings and precautions:

Take special care with VOCABRIA injection:

VOCABRIA injection can cause serious side effects. You must look out for certain symptoms while you are using VOCABRIA injection.

- **Severe skin reaction:** The serious skin reactions, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with VOCABRIA.
Stop using VOCABRIA and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions.
➔ Read the information in section 4 ('Possible side effects').
- **Allergic (hypersensitivity) reactions:** VOCABRIA contains cabotegravir, which is an integrase inhibitor. Integrase inhibitors can cause a serious allergic reaction known as a hypersensitivity reaction. You need to know about important signs and symptoms to look out for while you are receiving VOCABRIA. See Allergic reactions in Section 4.
- **Liver side effects:** Let your doctor know if you have any liver problems. Your liver function may need to be monitored. See also, Liver problems in Section 4.
- People taking combination therapy for HIV may find that their **body shape changes**. See 'Conditions you need to look out for' in Section 4.
- **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 (*auto-immune disorders*).

The symptoms of auto-immune disorders may develop many months after you start taking medicine to treat your HIV infection. See 'Conditions you need to look out for' in Section 4.

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- **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). VOCABRIA will not stop you from 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.

Other medicines and VOCABRIA Injection:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary and traditional medicines.)

Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking new ones. This includes herbal medicines and other medicines bought without a prescription.

Some medicines can affect how VOCABRIA works or make it more likely that you will have side effects. VOCABRIA can also affect how some other medicines work.

Don't take VOCABRIA with these medicines:

- carbamazepine, oxcarbazepine, phenobarbital, or phenytoin (also known as anticonvulsants used to treat epilepsy and prevent seizures)
- rifampicin or rifapentine (to treat some bacterial infections such as tuberculosis).

Tell your doctor if you are taking any of the medicines in the following list:

- medicines called antacids (e.g., magnesium, calcium and aluminium), to treat indigestion and heartburn (see also section 3)
- rifabutin (to treat some bacterial infections such as tuberculosis).

Tell your doctor or pharmacist if you are taking any of the above. Your doctor may decide that you need extra check-ups.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before you are given VOCABRIA Injections.

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

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 of VOCABRIA can pass into breast milk and harm your baby.

➔ Talk to your doctor immediately, if you're breast feeding, or thinking about breast feeding.

Driving and using machines:

VOCABRIA can make you dizzy and have other side effects that make you less alert.

- Don't drive or use machines unless you are sure you are not affected.

VOCABRIA injections contain mannitol:

Mannitol may have a mild laxative effect.

3. How VOCABRIA injection is given:

Do not share medicines prescribed for you with any other person.

Your doctor will schedule regular appointments according to the dosing schedule he will put you on. Check with your doctor if you are not sure.

You are not expected to give yourself a VOCABRIA injection. It will be given to you by a person who is qualified to do so.

As VOCABRIA injections must always be given with another HIV medicine (rilpivirine), you should also read the instructions for rilpivirine injection carefully. The leaflet is supplied in the rilpivirine injection carton.

You will be given VOCABRIA injection as a single injection, either once every month or once every 2 months, together with another injectable medicine called rilpivirine. Your doctor will advise you of your dosing schedule.

When you first start treatment with VOCABRIA, you and your doctor may decide to start directly with VOCABRIA injection.

The other option is that your doctor may advise you to take VOCABRIA tablets and rilpivirine tablets for one month (lead-in period) before your first VOCABRIA injection. Taking VOCABRIA and rilpivirine tablets before you receive VOCABRIA and rilpivirine injections will allow your doctor to test how well you tolerate these medicines.

Injection Schedule for Monthly Dosing:

Which medicine	When	
	First injection	Second injection onwards, every month
VOCABRIA	3 mL (600 mg)	2 mL (400 mg)
Rilpivirine	3 mL (900 mg)	2 mL (600 mg)

Injection Schedule for Every 2-month dosing:

Which medicine	When	
	First and second injections one month apart	Third injection onwards, every two months
VOCABRIA	3 mL (600 mg)	3 mL (600 mg)
Rilpivirine	3 mL (900 mg)	3 mL (900 mg)

How VOCABRIA injections are given:

A complete dose requires two injections:

- 2 mL of VOCABRIA + 2 mL of rilpivirine OR
- 3 mL of VOCABRIA + 3 mL of rilpivirine.

VOCABRIA and Rilpivirine injections are suspensions that do not need further dilution or reconstitution.

VOCABRIA and Rilpivirine are for intramuscular use (IM) only.

Both injections should be administered at separate gluteal injection sites.

The administration order is not important.

If you miss a VOCABRIA Injection:

If you are not able to receive your injection, your doctor may recommend you take VOCABRIA tablets instead, or a different HIV treatment until you can receive an injection again. Your doctor will advise you to take one tablet a day until your next VOCABRIA injection. If you miss your injection for more than 2 months, your doctor may give you another HIV oral medicine to take.

You will need regular blood tests:

For as long as you are using VOCABRIA injection, your doctor will arrange regular blood tests to measure the amount of HIV in your blood, and to check for side effects. There is more information about these side effects in Section 4 of this leaflet.

If you are given more VOCABRIA injections than you should:

A doctor or nurse will give this medicine to you, so it is unlikely that you will be given too much. If you are worried, tell the doctor or nurse.

If you miss an appointment for VOCABRIA injection:

If you miss an appointment to have your Injection, make another appointment as soon as possible.

If you stop VOCABRIA injections:

You should stay in regular contact with your doctor and don't stop using VOCABRIA without your Doctor's advice:

- VOCABRIA helps to control your condition, but it is not a cure for HIV infection. You need to keep using it as instructed by your doctor, to stop your illness from getting worse. Because VOCABRIA does not cure HIV infection, you may still develop other infections and illnesses linked to HIV infection.

4. Possible side effects:

VOCABRIA can have side effects.

Not all side effects reported for VOCABRIA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VOCABRIA, please consult your healthcare provider for advice.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of VOCABRIA or other medicines you are taking, or an effect of the HIV disease itself. So, 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 VOCABRIA injections.

Conditions you need to look out for:

Severe skin reactions:

Stop using VOCABRIA and seek medical attention immediately if you notice any of the following symptoms:

→ reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes. These skin reactions can be preceded by fever and flu-like symptoms (Steven-Johnson syndrome, toxic epidermal necrolysis).

Allergic reactions:

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- skin rash or itching
- a high temperature (fever)
- lack of energy (fatigue)
- raised and itchy rash (hives)
- swelling sometimes of the face or mouth (angioedema), causing difficulty in breathing
- muscle or joint aches.

Severe skin reactions and allergic reactions are very serious side effects. If you have them, you may have had a serious reaction to VOCABRIA Injection. You may need urgent medical attention or hospitalization.

Symptoms of Liver Injury:

Signs 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.

Your doctor will check for liver injury by doing blood tests before, during and after VOCABRIA treatment. If liver enzyme levels increase and remain high, your doctor may stop your VOCABRIA treatment.

- **Tell your doctor or pharmacist** if you notice any of these symptoms. These are all serious side effects. You may need urgent medical attention.

Symptoms of infection and inflammation:

Symptoms of infection and inflammation may develop and include:

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

If you get any symptoms of infection while you are using VOCABRIA injection, **tell your doctor immediately**. Do not take other medicines for the infection without your doctor's advice.

Your body shape may change:

Treatment with VOCABRIA may cause a loss of fat from your legs, arms and face (lipoatrophy). Your doctor should monitor for signs of lipoatrophy. Tell your doctor if you notice any loss of fat from your legs, arms, and face. When these signs occur, your doctor will assess if VOCABRIA should be stopped and your HIV treatment changed. If you stop receiving VOCABRIA, it may take several months to see any lost fat return. You may not regain all of your lost body fat.

The following side effects can also occur.**Frequent side effects:**

- headache
- injection site reactions, these were generally mild to moderate and became less frequent over time. Symptoms include:

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- Frequent: pain and discomfort, a hardened mass or lump; redness, itching, welling, warmth or bruising (which may include discolouration or a collection of blood under the skin)
 - Less frequent: numbness, minor bleeding, an abscess (collection of pus) or cellulitis (warmth, swelling or redness)
- feeling hot, (pyrexia), which may occur within one week after injection
 - depression
 - anxiety
 - abnormal dreams
 - difficulty in sleeping (insomnia)
 - dizziness
 - feeling sick (nausea)
 - being sick (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.

Less frequent side effects:

- feeling drowsy (somnolence)
- feeling lightheaded, during or following an injection. This may lead to fainting

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- changes in liver blood tests (increase in transaminases).

Other side effects that may show up in blood tests:

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

- an 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).

Other side effects that may occur:

- suicidal thoughts, suicidal attempt (mainly in patients who have had depression or mental health conditions before).

Tell your doctor or pharmacist if any of the side effects listed become **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc-org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VOCABRIA injections.

5. How to store VOCABRIA Injections:

Keep out of reach of children.

Unopened packs: Store at or below 30 °C. Do not freeze.

Open packs: Once the suspension has been drawn into the syringe, the injection should be administered as soon as possible but may be stored for up to 2 hours at room temperature. If 2 hours are exceeded, the medication, syringe and needle must be discarded.

Do not use after the expiry date on the label or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of the pack and other information:

What VOCABRIA Injections contain:

VOCABRIA 400 mg:

Each single dose 2 mL vial contains 400 mg cabotegravir (as cabotegravir free acid).

VOCABRIA 600 mg:

Each single dose 3 mL vial contains 600 mg cabotegravir (as cabotegravir free acid).

The other ingredients are macrogol, mannitol (E421), polysorbate 20, water for injections.

What VOCABRIA Injection looks like and contents of the pack:

VOCABRIA suspension for Injection is a white to light pink, free-flowing suspension.

A carton containing a single use Type I clear glass vials and sealed with bromobutyl rubber stoppers in two nominal fill presentations, 2 mL and 3mL. The stopper is secured with an aluminum overseal with a removeable plastic cap. The 2 mL fill presentation has a dark gray cap and the 3 mL fill presentation has an orange cap. The vial in the carton is a brown colour after terminal sterilization.

Not all presentations are available in the market.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

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