

**VOCABRIA 30 mg
Film-coated tablets
Patient Information Leaflet**

SCHEDULING STATUS:

S4

**VOCABRIA 30 mg
Film-coated tablets
Cabotegravir sodium**

Contains sugar (lactose monohydrate 163,59 mg/tablets)

Read all this leaflet carefully before you start taking VOCABRIA 30 mg.

- 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.
- VOCABRIA 30 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What VOCABRIA 30 mg is and what it is used for
2. What you need to know before you take VOCABRIA 30 mg
3. How to take VOCABRIA 30 mg
4. Possible side effects
5. How to store VOCABRIA 30 mg
6. Contents of the pack and other information.

1. What VOCABRIA 30 mg is and what it is used for:

VOCABRIA 30 mg tablets 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 30 mg is always given, in combination with another anti-retroviral medicine called rilpivirine 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 take VOCABRIA 30 mg:

Do not take VOCABRIA 30 mg:

- if you are allergic (hypersensitive) to cabotegravir or to any of the other ingredients of VOCABRIA 30 mg (listed in section 6)
- if you are taking any of these medicines:
 - 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)

Do not take VOCABRIA 30 mg with any of these medicines. Tell your doctor immediately if you are taking any of the above medicines.

Warnings and precautions:

Take special care with VOCABRIA:

VOCABRIA 30 mg can cause serious side effects. You must look out for certain symptoms while you are taking VOCABRIA 30 mg.

- **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're 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

- **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 30 mg 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.

VOCABRIA 30 mg tablets contain lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance, should not take VOCABRIA tablets.

VOCABRIA 30 mg contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Other medicines and VOCABRIA 30 mg:

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

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, 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 these. Your doctor may decide that you need extra check-ups (see section 3).

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 taking VOCABRIA 30 mg.

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 of VOCABRIA 30 mg can pass into breast milk and harm your baby.

Talk to your doctor immediately, if you're breastfeeding, or thinking about breastfeeding.

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.

3. How to take VOCABRIA 30 mg:

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

Always take VOCABRIA 30 mg exactly as your doctor has told you. Check with your doctor if you are not sure.

As VOCABRIA 30 mg must always be taken with another HIV medicine (rilpivirine), you should also follow the instructions for rilpivirine carefully. The leaflet is supplied in the rilpivirine carton.

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 one VOCABRIA 30 mg once a day for one month (lead-in period) before your first VOCABRIA injection. Taking VOCABRIA 30 mg for one month before you receive VOCABRIA injections will allow your doctor to test how well you tolerate these medicines.

Adults:

The usual dose of VOCABRIA 30 mg, is one tablet taken **once a day** for at least 28 days. VOCABRIA 30 mg tablets are always given with another HIV medicine tablet called rilpivirine.

How to take:

VOCABRIA 30 mg tablets should be swallowed whole with some liquid. VOCABRIA tablets can be taken with or without food, however, if you take VOCABRIA tablets at the same time as rilpivirine tablets, you must take them with a meal.

If you miss a VOCABRIA Injection:

If you are not able to receive your injection, your doctor may recommend you take VOCABRIA 30 mg 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.

You will need regular blood tests:

For as long as you are taking VOCABRIA 30 mg, 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.

Antacid medicines:

Antacids, to treat **indigestion** and **heartburn**, can stop VOCABRIA 30 mg tablets being absorbed into your body and make it less effective.

Antacids (e.g., magnesium, calcium or aluminium) should be taken at least 2 hours before or 4 hours after you take VOCABRIA tablets. Talk to your doctor for further advice on taking acid-lowering (antacid) medicines with VOCABRIA 30 mg tablets.

If you take more VOCABRIA 30 mg than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. If possible, show them the VOCABRIA 30 mg pack.

If you forget to take VOCABRIA 30 mg:

If you miss a dose, take it as soon as you remember. Then continue your treatment as before.

Don't take a double dose to make up for a missed dose.

If you stop taking VOCABRIA 30 mg:

You should stay in regular contact with your doctor and don't stop taking 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 taking it every day 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 taking VOCABRIA tablets.

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, stop taking VOCABRIA tablets and 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.

- ➔ Contact your doctor as soon as possible. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking VOCABRIA.

Severe skin reactions and allergic reactions are very serious side effects. If you have them, you may have had a serious reaction to VOCABRIA tablets. 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 take you off VOCABRIA tablets.

➔ **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 taking VOCABRIA tablets, **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 tablets may cause a loss of fat from 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 taking 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

- feeling hot, pyrexia)
- 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)
- 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 may occur:

- suicidal thoughts, suicidal attempts (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 tablets.

5. How to store VOCABRIA 30 mg:

Keep out of reach of children.

Store at or below 30 °C.

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 30 mg contains:

Each film-coated tablet contains 30 mg of cabotegravir (as cabotegravir sodium).

The other ingredients are:

Tablet core: hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycollate.

Tablet coating: hypromellose, macrogol, titanium dioxide (E171).

What VOCABRIA 30 mg looks like and contents of the pack:

VOCABRIA 30 mg film coated tablet, is a white, film-coated, oval tablet.

A carton containing 30 tablets which are packed into white HDPE (high density polyethylene) bottles with child-resistant closures that include a polyethylene faced induction heat seal liner.

Holder of Certificate of Registration:

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