
PATIENT INFORMATION LEAFLET

VOCABRIA 30 mg film coated tablets

cabotegravir

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again. If you have any questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.

In this leaflet

- 1. What VOCABRIA is and what it is used for**
- 2. Before you take VOCABRIA**
- 3. How to take VOCABRIA**
- 4. Possible side effects**
- 5. How to store VOCABRIA**
- 6. Further information**

1. What VOCABRIA is and what it is used for

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

VOCABRIA contains the active ingredient cabotegravir, which belongs to a group of anti-retroviral 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 cells that are important in helping your body to fight infection.

VOCABRIA 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. Before you take VOCABRIA

Don't take VOCABRIA

- if you're allergic (*hypersensitive*) to **cabotegravir** or to any of the other ingredients of VOCABRIA (listed in Section 6).
- If you're 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).

➔ **Don't take VOCABRIA** with any of these medicines. Tell your doctor.

Conditions you need to look out for

VOCABRIA can cause serious side effects. You must look out for certain symptoms while you are taking VOCABRIA and tell your doctor.

Allergic reaction

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**.

Symptoms of infection

See '*Conditions you need to look out for*' in **Section 4**.

Take special care with VOCABRIA

Let your doctor know if you have liver problems. Your liver function may need to be monitored. (*See also 'Liver problems' in section 4*).

Other medicines and VOCABRIA

Tell your doctor or pharmacist if you're taking any other medicines, if you've 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).
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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.

Pregnancy and breast-feeding

If you are **pregnant**, or **think you could be**, or if you are **planning to have a baby**, **don't take VOCABRIA** without checking with your doctor. **Your doctor** will consider the benefit to you and the risk to your baby of taking VOCABRIA while you're pregnant.

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're not affected.

While you're taking VOCABRIA

You will need regular blood tests

For as long as you're taking VOCABRIA, your doctor will arrange regular blood tests to check for side effects. There is more information about these side effects in **Section 4** of this leaflet.

Stay in regular contact with your doctor

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.

➔ **Keep in touch with your doctor, and don't stop taking VOCABRIA** without your doctor's advice.

3. How to take VOCABRIA

Always take VOCABRIA exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

As VOCABRIA 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.

How much to take

Adults

Oral dosing with VOCABRIA

The usual dose of VOCABRIA is one tablet (30 mg cabotegravir) taken **once a day**.

VOCABRIA tablets are always given with another HIV medicine tablet called rilpivirine.

How to take

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

Initial treatment with VOCABRIA

When you first start treatment with VOCABRIA, your doctor will advise you to take one VOCABRIA tablet once a day for one month (lead-in period) before your first VOCABRIA injection. VOCABRIA tablets are always given with another HIV medicine tablet called rilpivirine.

Taking VOCABRIA and rilpivirine tablets for one month before you receive VOCABRIA and rilpivirine injections will allow your doctor to test how well you tolerate these medicines.

Which medicine	When	Dose
VOCABRIA	For 1 Month (at least 28 days)	30 mg tablet once a day
Rilpivirine	For 1 Month (at least 28 days)	25 mg tablet once a day

If you will miss a VOCABRIA Injection

If you are not able to receive your injection, your doctor may recommend you take VOCABRIA tablets instead, until you can receive an injection again. Your doctor will advise you to take one tablet a day until you next VOCABRIA injection.

Antacid medicines

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

Antacids should be taken at least 2 hours before or 4 hours after you take VOCABRIA. Talk to your doctor for further advice on taking acid-lowering (antacid) medicines with VOCABRIA.

If you forget to take VOCABRIA

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 take too much VOCABRIA

If you take too many tablets of VOCABRIA, **contact your doctor or pharmacist for advice**. If possible, show them the VOCABRIA pack.

Don't stop VOCABRIA without advice

Take VOCABRIA for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

When you're 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. If you get any of these effects, and if they are severe, your doctor may advise you to stop taking VOCABRIA.

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

→ **It is important to read the information** in '*Conditions you need to look out for*', later in this section.

Allergic Reactions

These are uncommon in people taking VOCABRIA. Signs include:

- skin rash
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- 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.

Very common side effects

These may affect **more than 1 in 10** people:

- Headache
- Feeling hot (*pyrexia*)

Common side effects

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

- depression
 - anxiety
 - abnormal dreams
 - difficulty in 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*)
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- generally feeling unwell (*malaise*)
 - weight gain

Uncommon side effects

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

- feeling drowsy (*somnolence*)
- 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*)
- 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*).

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

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

Conditions you need to look out for

Some other conditions may develop during HIV treatment.

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.

➔ **Tell your doctor or pharmacist** if you notice any of these symptoms.

Symptoms of Infection

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections).

If you get any symptoms of infection

➔ **Tell your doctor immediately.** Don't take other medicines for the infection without your doctor's advice.

5. How to Store VOCABRIA

The Storage conditions are detailed on the packaging.

Keep out of the sight and reach of children.

Do not take VOCABRIA after the expiry date shown on the pack.

Don't throw away any medicines in wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. This will help to protect the environment.

6. Further information**What VOCABRIA contains**

The active substance is cabotegravir (as cabotegravir sodium). Each tablet contains 30 mg cabotegravir.

The other ingredients are:

Tablet core:

Lactose Monohydrate
Microcrystalline Cellulose
Hypromellose
Sodium Starch Glycolate
Magnesium Stearate

Tablet coating

Hypromellose
Titanium Dioxide (E171)
Macrogol

What VOCABRIA looks like and contents of the pack

The 30 mg tablets are White, oval, film-coated tablets marked with SV CTV on one side.

VOCABRIA tablets are supplied in HDPE (high density polyethylene) bottles with child-resistant closures. Each bottle contains 30 film-coated tablets.

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