

Package leaflet: Information for the patient

Vocabria 30 mg film-coated tablets cabotegravir

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vocabria tablets are and what they are used for
2. What you need to know before you take Vocabria tablets
3. How to take Vocabria tablets
4. Possible side effects
5. How to store Vocabria tablets
6. Contents of the pack and other information

1. What Vocabria is and what it is used for

Vocabria tablets contain the active ingredient cabotegravir. Cabotegravir belongs to a group of anti-retroviral medicines called *integrase inhibitors (INIs)*.

Vocabria tablets are used to treat HIV (human immunodeficiency virus) infection in adults aged 18 years and over who are also taking another antiretroviral medicine called rilpivirine and whose HIV-1 infection is under control.

Vocabria tablets do not cure HIV infection; they keep 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.

Your doctor will advise you to take Vocabria tablets before you are given a Vocabria injection for the first time.

If you are being given Vocabria injection, but you are not able to receive your injection, your doctor may also recommend that you take Vocabria tablets instead, until you can receive the injection again.

Vocabria tablets are always given in combination with another anti-retroviral medicine called *rilpivirine tablets* to treat HIV infection. Vocabria and rilpivirine tablets will replace your current antiretroviral medicines. Refer to the rilpivirine package leaflet for information on that medicine.

2. What you need to know before you take Vocabria

Do not take Vocabria tablets:

- if you are **allergic** (*hypersensitive*) to cabotegravir or any of the other ingredients of this medicine (listed in section 6).

- if you are taking any of these medicines, as they may affect the way Vocabria works:
 - **carbamazepine, oxcarbazepine, phenytoin, phenobarbital** (medicines to treat epilepsy and prevent fits)
 - **rifampicin or rifapentine** (medicines to treat some bacterial infections such as tuberculosis).

➔ If you think this applies to you, **tell your doctor**.

Warnings and precautions

Allergic reaction

Vocabria contains cabotegravir, which is an integrase inhibitor. Integrase inhibitors including cabotegravir 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 taking Vocabria.

➔ **Read the information** in section 4 of this leaflet.

Liver problems including hepatitis B and/or C

Tell your doctor if you have or have had problems with your liver, including hepatitis B and/or C. Your doctor may evaluate how severe your liver disease is before deciding if you can take Vocabria.

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you're taking Vocabria. These include:

- symptoms of infections
- symptoms of liver damage.

➔ **Read the information** in section 4 of this leaflet ('Possible side effects').

If you get any symptoms of infection or liver damage:

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

Children and adolescents

This medicine is not for use in children or adolescents less than 18 years of age, because it has not been studied in these patients.

Other medicines and Vocabria tablets

Tell your doctor if you are taking, have recently taken or might take any other medicines including other medicines bought without a prescription.

Vocabria must not be taken with some other medicines (see 'Do not take Vocabria tablets' earlier in section 2):

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.

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

- **Medicines called antacids, to treat indigestion and heartburn**. Antacids can stop the medicine in Vocabria tablets from being absorbed into your body.
Do not take these medicines in the 2 hours before you take Vocabria or for at least 4 hours after you take it.
- **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 breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby:

➔ **Talk to your doctor** before taking Vocabria .

Pregnancy

- **Vocabria is not recommended during pregnancy.** If needed, your doctor will consider the benefit to you and the risk to your baby of taking Vocabria while you're pregnant. If you are planning to have a baby, **talk to your doctor in advance**
- If you have become pregnant do not stop taking Vocabria without consulting your doctor.

Breast-feeding

Breast-feeding is **not recommended** in women living with HIV because HIV infection can be passed on to the baby in breast milk.

It is not known whether the ingredients of Vocabria tablets can pass into breast milk.

If you're breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

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.

Important information about some of the ingredients of Vocabria

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Vocabria

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Vocabria tablets must always be taken with another HIV medicine (rilpivirine tablets). You should also follow the instructions for rilpivirine carefully. The leaflet is supplied in the rilpivirine carton.

Dosing schedule for Vocabria tablets followed by monthly injections

Which medicine	When		
	During month 1 (at least 28 days)	At month 2 following one month of tablets	Month 3 onwards
Vocabria	30 mg tablet once daily	600 mg injection	400 mg injection monthly
Rilpivirine	25 mg tablet once daily	900 mg injection	600 mg injection monthly

Dosing schedule for Vocabria tablets followed by every 2 month injections

Which medicine	When		
	Month 1 (at least 28 days)	At Month 2 and Month 3 following one month of tablets	Month 5 onwards
Vocabria	30 mg tablet once a day	600 mg injection	600 mg injection every 2 months
Rilpivirine	25 mg tablet once a day	900 mg injection	900 mg injection every 2 months

When you first start treatment with Vocabria, you and your doctor may decide to either start treatment with Vocabria tablets or start treatment directly with a Vocabria injection:

If you decide to start treatment with tablets, your doctor will tell you:

- to take one 30 mg Vocabria tablet and one 25 mg rilpivirine tablet, once a day, for approximately **one month**.
- after that, receive **monthly or every 2 month injections**.

The first month of Vocabria and rilpivirine tablets is called the oral **lead-in-period**. It allows your doctor to assess whether it's appropriate to proceed with injections.

How to take the tablets

Vocabria tablets should be swallowed with a small amount of water.

Vocabria can be taken with or without food. However, when Vocabria is taken at the same time as rilpivirine, both tablets should be taken with a meal.

If you cannot receive your Vocabria injection

If you are not able to receive your Vocabria injection, your doctor may recommend you take Vocabria tablets or another HIV treatment instead, until you can receive an injection again.

Antacid medicines

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

Do not take an antacid during the 2 hours before you take a Vocabria tablet or for at least 4 hours after you take it. Talk to your doctor for further advice on taking acid-lowering (antacid) medicines with Vocabria tablets.

If you take more Vocabria than you should

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

If you forget to take Vocabria

If you notice within 12 hours of the time you usually take Vocabria, take the missed tablet as soon as possible. If you notice after 12 hours, then skip that dose and take the next dose as usual.

➔ **Do not take a double dose** to make up for a forgotten tablet.

If you vomit less than 4 hours after taking Vocabria, take another tablet. If you vomit more than 4 hours after taking Vocabria you do not need to take another tablet until your next scheduled dose.

Don't stop taking Vocabria without advice from your doctor

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

Vocabria contains cabotegravir, which is an integrase inhibitor. Integrase inhibitors including cabotegravir can cause a serious allergic reaction known as a hypersensitivity reaction.

If you get any of the following symptoms:

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

➔ **See a doctor straight away.** Your doctor may decide to carry out tests to check 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*)
- generally feeling unwell (*malaise*)
- weight gain.

Uncommon side effects

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

- suicide attempt and suicidal thoughts (particularly in patients who have had depression or mental health problems before)
- allergic reaction (*hypersensitivity*)
- hives (*urticaria*)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- 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)
- changes in liver blood tests (increase in *transaminases* or increase in *bilirubin*).

Other side effects that may show up in blood tests

- an increase in lipases (a substance produced by the pancreas)

Other possible side effects

People taking Vocabria and rilpivirine therapy for HIV may get other side effects.

Pancreatitis

If you get severe pain in the abdomen (tummy), this may be caused by inflammation of your pancreas (pancreatitis).

➔ **Tell your doctor**, especially if the pain spreads and gets worse.

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 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 and inflammation or if you notice any of the symptoms above:

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vocabria

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated after EXP on the carton and bottle. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vocabria contains

The active substance is cabotegravir. Each tablet contains 30 mg cabotegravir.

The other ingredients are:

Tablet core

Lactose Monohydrate
Microcrystalline Cellulose (E460)
Hypromellose (E464)
Sodium Starch Glycolate
Magnesium Stearate

Tablet coating

Hypromellose (E464)
Titanium Dioxide (E171)
Macrogol (E1521)

What Vocabria looks like and contents of the pack

Vocabria film-coated tablets are white, oval, film-coated tablets, debossed with 'SV CTV' on one side.

The film-coated tablets are provided in bottles closed with child-resistant closures.

Each bottle contains 30 film-coated tablets.

Marketing Authorisation Holder

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Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name Vocabria 30mg Tablets

Reference number 35728/0055

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in June 2023.