

▼ 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.

VOCABRIA TABLETS

cabotegravir (as cabotegravir sodium) 30 mg film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VOCABRIA TABLETS. 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 taking VOCABRIA TABLETS against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What VOCABRIA TABLETS are used for

VOCABRIA TABLETS are used to treat Human Immunodeficiency Virus (HIV) infection in adults.

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

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 cell

that are important in helping your body to fight infection.

VOCABRIA TABLETS are always given in combination with another antiretroviral 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 them.

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.

VOCABRIA TABLETS are not addictive.

This medicine is available only with a doctor's prescription

Before you take VOCABRIA TABLETS

When you must not take it

Do not take VOCABRIA TABLETS if you have an allergy to:

- any medicine containing cabotegravir
- 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
- 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 aches

Do not take VOCABRIA TABLETS 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 this medicine 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 start taking this medicine, talk to your doctor.

Before you start to take it

Some other conditions may develop during HIV treatment.

- **Symptoms of infection and inflammation**

People with a 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 a gain 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 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:

- 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 VOCABRIA TABLETS.

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 VOCABRIA TABLETS while 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 TABLETS can pass into breast milk and harm your baby.

If you have not told your doctor about any of the above, tell him/her before you start taking VOCABRIA TABLETS.

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 VOCABRIA TABLETS may interfere with each other. These include:

- carbamazepine, oxcarbazepine, phenobarbital, or phenytoin (also known as anticonvulsants used to treat epilepsy and prevent seizures)
- rifampicin or rifampentine (to treat some bacterial infections such as tuberculosis)
- rifabutin (to treat some bacterial infections such as tuberculosis)
- medicines called antacids to treat indigestion and heartburn.
- medicines for the treatment of hepatitis C.

These medicines may be affected by VOCABRIA TABLETS or may affect how well it works. 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 a void while taking this medicine.

How to take VOCABRIA TABLETS

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

As VOCABRIA TABLETS must always be taken with another HIV medicine (rilpivirine), you should also follow the instructions for rilpivirine carefully.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

The usual dose of VOCABRIA TABLETS is one tablet (30 mg cabotegravir) taken once a day for one month (or at least 28 days).

VOCABRIA TABLETS are always given with another HIV medicine called rilpivirine 25 mg tablets.

VOCABRIA TABLETS and rilpivirine tablets are taken for one month (oral lead-in) before you receive cabotegravir injection and rilpivirine injection, to allow your doctor to test how well you tolerate these medicines.

How to take it

VOCABRIA 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.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you need to take an antacid, take it at least 2 hours before or 4 hours after you take your VOCABRIA TABLET.

How long to take it

Initial treatment with VOCABRIA TABLETS

When you first start treatment, your doctor will advise you to take one VOCABRIA TABLET together with one rilpivirine tablet, once a day, for one month (lead-in period) before you start your first cabotegravir injection.

If you miss your monthly cabotegravir injection

If you are not able to receive your monthly cabotegravir injection, your doctor may recommend you instead take one VOCABRIA TABLET with one rilpivirine tablet, until you can receive the injections again.

Continue taking your medicine for as long as your doctor tells you.

Don't stop unless your doctor advises you to.

If you forget to take it

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

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or

go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too many VOCABRIA TABLETS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using VOCABRIA TABLETS

Things you must do

- **You will need regular blood tests**

For as long as you're taking VOCABRIA TABLETS, your doctor will arrange regular blood tests to check for side effects.

- **Stay in regular contact with your doctor**

VOCABRIA TABLETS help 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 TABLETS do not cure HIV infection, you may still develop other infections and illnesses linked to HIV infection.

Keep in contact with your doctor, and don't stop taking VOCABRIA TABLETS 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). VOCABRIA TABLETS 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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking VOCABRIA TABLETS.

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

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

It may affect other medicines used during surgery.

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

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take VOCABRIA TABLETS to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

Don't drive or operate machinery unless you are sure you are not affected.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking VOCABRIA TABLETS.

This medicine helps most people with HIV, but it 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're being treated for HIV, it can be hard to tell whether a symptom is a side effect of VOCABRIA TABLETS 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. If you get any of these effects, and if they are severe, your doctor may advise you to stop taking VOCABRIA TABLETS.

As well as the effects listed below for VOCABRIA TABLETS, 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.

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 (feelings of deep sadness and unworthiness)
- anxiety
- abnormal dreams
- difficulty in sleeping (insomnia)
- dizziness
- feeling sick (nausea)
- being sick (vomiting)
- stomach (abdominal) pain or discomfort
- wind (flatulence)
- diarrhoea

- rash
- muscle pain (myalgia)
- lack of energy (fatigue)
- feeling weak (asthenia)
- generally feeling unwell (malaise)

Uncommon side effects

These may affect up to 1 in 100 people:

- feeling drowsy (somnolence)
- liver damage
- weight gain
- 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 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.

Other side effects not listed above may also occur in some people.

After using VOCABRIA TABLETS

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store VOCABRIA TABLETS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking 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

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

Ingredients

The active ingredient in VOCABRIA TABLETS is cabotegravir (as cabotegravir sodium). Each tablet contains 30 mg cabotegravir.

The other ingredients are:

- lactose monohydrate
- microcrystalline cellulose
- hypromellose
- sodium starch glycolate
- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol

Supplier

VOCABRIA TABLETS is supplied in Australia by:

ViiV Healthcare Pty Ltd
Level 4, 436 Johnston Street
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Australia

AUST R 323721.

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This leaflet was prepared on 21
January 2021.

Version 1.0