

# VOCABRIA

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. Why am I taking VOCABRIA?

VOCABRIA contains the active ingredient cabotegravir. VOCABRIA is used to treat Human Immunodeficiency Virus (HIV) infection in adults.

For more information, see Section [1. Why am I taking VOCABRIA?](#) in the full CMI.

## 2. What should I know before I take VOCABRIA?

Do not use VOCABRIA if you have ever had an allergic reaction to cabotegravir or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take VOCABRIA?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with VOCABRIA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I take VOCABRIA?**

- VOCABRIA should be taken once a day and must always be taken with another HIV medicine (rilpivirine).
- Take VOCABRIA for as long as your doctor tells you. Don't stop unless your doctor advises you to.

More instructions can be found in Section [4. How do I take VOCABRIA?](#) in the full CMI.

### **5. What should I know while taking VOCABRIA?**

|                             |  |
|-----------------------------|--|
| <b>Things you should do</b> | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist</li></ul> |
|-----------------------------|--|

|                                    |  |
|------------------------------------|--|
|                                    | <p>you visit that you are taking VOCABRIA.</p> <ul style="list-style-type: none"> <li>• Have regular blood tests and stay in regular contact with your doctor.</li> <li>• Continue to protect people as VOCABRIA may not stop you passing HIV infection on to others.</li> </ul> |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"> <li>• Do not miss any doses of VOCABRIA or stop taking it without talking to your doctor.</li> </ul>  |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"> <li>• VOCABRIA can make you dizzy and have other side effects that make you less alert.</li> <li>• Do not drive or use machines unless you are sure you are not affected.</li> </ul>  |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>• Keep your tablets in a cool, dry place where the temperature stays below 30°C.</li> <li>• Keep your tablets in the bottle until it is time to take them.</li> </ul>   |

For more information, see Section [5. What should I know while taking VOCABRIA?](#) in the full CMI.

## **6. Are there any side effects?**

The following common side effects may occur when taking VOCABRIA: headache, feeling hot, diarrhoea, nausea, vomiting, stomach pain, wind, dizziness, depression, anxiety, abnormal dreams, insomnia, muscle pain, rash and fatigue.

Contact your doctor promptly if you develop an allergic reaction or if you have liver problems.

Whilst very rare, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are serious and life-threatening. Contact your doctor straight away if you develop painful red or purple skin, blisters on your skin, mouth, nose and genitals and red, painful, watery eyes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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](http://www.tga.gov.au/reporting-problems).

## VOCABRIA

**Active ingredient:** *cabotegravir (as cabotegravir sodium)*

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using VOCABRIA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VOCABRIA.**

**Where to find information in this leaflet:**

- [1. Why am I taking VOCABRIA?](#)
- [2. What should I know before I take VOCABRIA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take VOCABRIA?](#)
- [5. What should I know while taking VOCABRIA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I taking VOCABRIA?**

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

**VOCABRIA is used to treat Human Immunodeficiency Virus (HIV) infection in adults.**

VOCABRIA does 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 is 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 are not addictive.

## 2. What should I know before I take VOCABRIA?

### Warnings

#### Do not use VOCABRIA if:

- you are allergic to cabotegravir or any of the ingredients listed at the end of this leaflet.
- if you are taking rifampicin or rifapentine (to treat some bacterial infections such as tuberculosis) or phenytoin, phenobarbital, carbamazepine or oxcarbazepine (anticonvulsants used to treat epilepsy and prevent seizures)
- always check the ingredients to make sure you can use this medicine.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

#### Check with your doctor if you:

- have any other medical conditions, such as liver problems. **Your liver function will be monitored by your doctor during treatment with VOCABRIA.**
- take any medicines for any other condition

#### 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 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.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)



## **Pregnancy and breastfeeding**

**Check with your doctor if you are pregnant or intend to become pregnant.**

Your doctor can discuss with you the risks and benefits, to you and your baby, of receiving VOCABRIA while pregnant.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

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 can pass into breast milk and harm your baby.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines and VOCABRIA 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 rifapentine (to treat some bacterial infections such as tuberculosis)

- rifabutin (to treat some bacterial infections such as tuberculosis)
- medicines call antacids to treat indigestion and heartburn.
- medicines for the treatment of hepatitis C.

These medicines may be affected by VOCABRIA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VOCABRIA.**

## **4. How do I take VOCABRIA?**

When you first start treatment with cabotegravir, you and your doctor may decide to start directly with the cabotegravir injection and rilpivirine injection, CABENUVA.

Alternatively, your doctor may advise you to take one VOCABRIA tablet and one rilpivirine tablet once a day for one month (lead-in period) before you receive your cabotegravir injection and rilpivirine injection. Taking VOCABRIA and rilpivirine tablets will allow your doctor to test how well you tolerate these medicines.

### **How much to take**

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

- VOCABRIA is always given with another HIV medicine called rilpivirine 25 mg tablets.
- Follow the instructions provided and use VOCABRIA until your doctor tells you to stop.

## **When to take VOCABRIA**

- Take VOCABRIA once a day at the same time each day. Taking your tablet 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 to take VOCABRIA**

- VOCABRIA should be swallowed whole with some liquid.
- VOCABRIA 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.

## **If you will miss your cabotegravir injection**

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

## **If you forget to take VOCABRIA**

VOCABRIA should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

## **If you take too much**

If you think that you have taken too many tablets you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while taking VOCABRIA?

### Things you should do

- **Have regular blood tests**

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

- **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 contact with your doctor, and don't stop taking VOCABRIA 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 may 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.

## **Call your doctor straight away if you:**

- Become pregnant while taking VOCABRIA.

Remind any doctor, dentist or pharmacist you visit that you are using VOCABRIA.

## **Things you should not do**

- Do not stop using this medicine or lower the dosage without checking with your doctor.
- Do not take VOCABRIA 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.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how VOCABRIA affect you.**

VOCABRIA may cause dizziness in some people or have other side effects that make you less alert.

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

## **Looking after your medicine**

- Keep your tablets in the bottle until it is time to take them.
- Keep your tablets in a cool, dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about 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 combination therapy for HIV.

**Less serious side effects**

| <b>Less serious side effects</b>  | <b>What to do</b>   |
|---|---|
| <p><b>Nervous system and psychiatric disorders:</b></p> <p><i>Very common*</i></p> <ul style="list-style-type: none"> <li>• Headache</li> </ul> <p><i>Common**</i></p> <ul style="list-style-type: none"> <li>• Dizziness</li> <li>• Depression (feelings of deep sadness and unworthiness)</li> <li>• Anxiety</li> <li>• Abnormal dreams</li> <li>• Difficulty in sleeping (insomnia)</li> </ul> <p><i>Uncommon***</i></p> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> |



| Less serious side effects   | What to do |
|---|------------|
| <ul style="list-style-type: none"> <li>• Feeling drowsy (somnolence)</li> </ul> <p><b>Gastrointestinal disorders:</b></p> <p><i>Common</i></p> <ul style="list-style-type: none"> <li>• Diarrhoea</li> <li>• Feeling sick (nausea)</li> <li>• Being sick (vomiting)</li> <li>• Stomach (abdominal) pain or discomfort</li> <li>• Wind (flatulence)</li> </ul> <p><b>General disorders:</b></p> <p><i>Very common</i></p> <ul style="list-style-type: none"> <li>• Feeling hot (pyrexia)</li> </ul> <p><i>Common</i></p> <ul style="list-style-type: none"> <li>• Lack of energy (fatigue)</li> <li>• Feeling weak (asthenia)</li> <li>• Generally feeling unwell (malaise)</li> </ul> <p><b>Other:</b></p> <p><i>Common</i></p> <ul style="list-style-type: none"> <li>• Rash</li> <li>• Muscle pain (myalgia)</li> </ul> |            |

| <b>Less serious side effects</b>   | <b>What to do</b> |
|--|-------------------|
| <p data-bbox="204 259 453 304"><i>Uncommon</i></p> <ul data-bbox="204 340 504 394" style="list-style-type: none"> <li data-bbox="204 340 504 394">• Weight gain</li> </ul> <p data-bbox="204 439 743 546"><b>Side effects that may show up in blood tests:</b></p> <ul data-bbox="204 582 778 1227" style="list-style-type: none"> <li data-bbox="204 582 778 743">• increase in bilirubin (a substance produced by the liver) in the blood</li> <li data-bbox="204 761 778 922">• an increase in lipase (an enzyme produced by the pancreas).</li> <li data-bbox="204 940 778 1227">• an increase in the level of enzymes produced in the muscles (creatine phosphokinase, creatinine)</li> </ul> |                   |

\*Very common: may affect more than 1 in 10 people

\*\* Common: may affect up to 1 in 10 people

\*\*\*Uncommon: may affect up to 1 in 100 people

## **Serious side effects**

| <b>Serious side effects</b>   | <b>What to do</b>   |
|---|---|
| <p data-bbox="204 1803 600 1861"><b>Allergic reaction:</b></p> <ul data-bbox="204 1888 778 1995" style="list-style-type: none"> <li data-bbox="204 1888 778 1995">• Rash, itching or hives on skin</li> </ul> | <p data-bbox="810 1803 1378 2029"><b>Call your doctor straight away, or go straight to the Emergency Department at your</b></p> |

| <b>Serious side effects</b>  | <b>What to do</b>   |
|--|---|
| <ul style="list-style-type: none"> <li>● High temperature (fever)</li> <li>● Lack of energy (fatigue)</li> <li>● Swelling of the face, lips, tongue or other parts of the body</li> <li>● Wheezing or difficulty breathing</li> <li>● Shortness of breath</li> <li>● Muscle or joint aches</li> </ul> <p><b>Liver disorders:</b></p> <p><i>Uncommon***</i></p> <ul style="list-style-type: none"> <li>● Changes in liver blood tests (increase in transaminases)</li> <li>● 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)</li> </ul> <p><b>Psychological</b></p> <p><i>Uncommon***</i></p> <ul style="list-style-type: none"> <li>● suicidal thoughts*</li> </ul> | <p><b>nearest hospital if you notice any of these serious side effects.</b></p> |

| <b>Serious side effects</b>   | <b>What to do</b> |
|---|-------------------|
| <ul style="list-style-type: none"> <li>● Suicidal attempt*</li> </ul> <p>*mainly in patients who have had depression or mental health problems before.</p> <p><b>Skin and subcutaneous tissue disorders</b></p> <ul style="list-style-type: none"> <li>● Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are serious life-threatening conditions which usually start with flu-like symptoms. A few days later other symptoms appear including: <ul style="list-style-type: none"> <li>○ painful red or purple skin that looks burned and peels off</li> <li>○ blisters on your skin, mouth, nose and genitals</li> <li>○ red, painful, watery eyes</li> </ul> </li> </ul> |                   |

\*\*\*Uncommon: may affect up to 1 in 100 people

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What VOCABRIA contains**

|  |  |
|--|--|
| <b>Active ingredient<br/>(main ingredient)</b> | Cabotegravir (as cabotegravir sodium).<br>Each tablet contains 30 mg cabotegravir. |
| <b>Other ingredients</b>                       | lactose monohydrate  |

**(inactive ingredients)**

microcrystalline cellulose  
hypromellose  
sodium starch glycolate  
magnesium stearate  
titanium dioxide  
macrogol

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What VOCABRIA looks like**

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

AUST R 323721

## **Who distributes VOCABRIA**

ViiV Healthcare Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, VIC 3067

Australia

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