

# RUKOBIA

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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 using RUKOBIA?

RUKOBIA contains fostemsavir (as fostemsavir trometamol which is changed in the body to the active form of the drug, temsavir. RUKOBIA is used to treat Human Immunodeficiency Virus (HIV) infection in adults.

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

## 2. What should I know before I use RUKOBIA?

Do not use if you have ever had an allergic reaction to fostemsavir trometamol 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 use RUKOBIA?](#) in the full CMI.

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

Some medicines may interfere with RUKOBIA 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 use RUKOBIA?**

- The usual dose of RUKOBIA is one 600 mg tablet, twice a day.
- RUKOBIA should be swallowed whole, with some liquid. Don't chew, crush or split the tablets.
- You can take RUKOBIA with or without food.

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

## 5. What should I know while using RUKOBIA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● <b>Remind any doctor, dentist or pharmacist you visit that you are using RUKOBIA.</b></li><li>● <b>If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</b></li><li>● <b>For as long as you're taking RUKOBIA, your doctor will arrange regular blood tests to check for side effects.</b></li><li>● <b>Keep in contact with your doctor, and don't stop taking RUKOBIA without your doctor's advice.</b></li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● <b>Do not take RUKOBIA to treat any other complaints unless your doctor tells you to.</b></li><li>● <b>Do not stop taking your medicine or lower the</b></li></ul>

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>● <b>Remind any doctor, dentist or pharmacist you visit that you are using RUKOBIA.</b></li> <li>● <b>If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</b></li> <li>● <b>For as long as you're taking RUKOBIA, your doctor will arrange regular blood tests to check for side effects.</b></li> <li>● <b>Keep in contact with your doctor, and don't stop taking RUKOBIA without your doctor's advice.</b></li> </ul>
	<p>dosage without checking with your doctor.</p>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● <b>Don't drive or operate machinery unless you are sure you are not affected.</b></li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● <b>Keep your tablets in a cool dry place where the temperature stays below 30°C.</b></li> </ul>

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>● <b>Remind any doctor, dentist or pharmacist you visit that you are using RUKOBIA.</b></li> <li>● <b>If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</b></li> <li>● <b>For as long as you're taking RUKOBIA, your doctor will arrange regular blood tests to check for side effects.</b></li> <li>● <b>Keep in contact with your doctor, and don't stop taking RUKOBIA without your doctor's advice.</b></li> </ul>
	<ul style="list-style-type: none"> <li>● <b>Keep your tablets in the bottle until it is time to take them.</b></li> <li>● <b>Do not store RUKOBIA or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.</b></li> </ul>

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

## 6. Are there any side effects?

The most common side effects are feeling sick (nausea), diarrhoea, being sick (vomiting), stomach pain (abdominal pain), headache and rash. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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).

## RUKOBIA

**Active ingredient:** *fostemsavir 600 mg (as fostemsavir trometamol)* extended-release tablets

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using RUKOBIA. **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 RUKOBIA.**

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

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

## 1. Why am I using RUKOBIA?

**RUKOBIA contains fostemsavir trometamol, which is changed in the body to the active form of the drug, temsavir.** RUKOBIA is a type of medicine known as an anti-retroviral. It belongs to a group of drugs called attachment inhibitors (AIs). It works by binding to the virus and then blocking HIV from attaching to, and infecting, your blood cells.

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

There is not enough information to recommend the use of this medicine for people under the age of 18 years.

RUKOBIA doesn't cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level. RUKOBIA also increases the CD4 cell count in your blood. HIV causes a reduction in the number and function of CD4 cells in your body. CD4 cells are a type of white blood cell that are important in helping your body to fight infection.

RUKOBIA is used, in combination with other anti-retroviral medicines (combination therapy), to treat HIV infection in adults who have had difficulty in controlling their HIV with many other antiretroviral medicines.

## 2. What should I know before I use RUKOBIA?

### Warnings

#### Do not use RUKOBIA if:

- you are allergic to fostemsavir trometamol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not take this medicine if you are taking of these medicines; **carbamazepine**, or **phenytoin** (also known as anticonvulsants used to treat epilepsy and prevent seizures), **mitotane** (used to treat several types of cancer), **enzalutamide** (to treat prostate cancer), **rifampicin** (to treat some bacterial infections such as tuberculosis) or **products that contain St John's wort** (*Hypericum perforatum*) (a herbal product).

#### Check with your doctor if you:

- have any other medical conditions including if you have or had a heart problem, or if you notice any unusual changes in your heartbeat (such as beating too fast or too slow). RUKOBIA can affect heart rhythm.
- if you have, or had, liver disease, including hepatitis B or C. Talk to your doctor if this applies to you. You

may need extra check-ups, including blood tests, while you're taking your medication.

- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.

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.

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

Your doctor can discuss with you the risks and benefits, to you and your baby, of receiving RUKOBIA 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 RUKOBIA can pass into breast milk and harm your baby.

## **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.

### 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 may decrease the effectiveness of RUKOBIA. Don't take RUKOBIA with the following medicines (without first consulting with your doctor):

- carbamazepine, or phenytoin (also known as anticonvulsants), to treat epilepsy and prevent seizures
- mitotane, to treat several types of cancer
- enzalutamide, to treat prostate cancer
- rifampicin, to treat some bacterial infections such as tuberculosis
- products that contain St John's wort (*Hypericum perforatum*) (a herbal product).

RUKOBIA is not recommended with elbasvir/grazoprevir, to treat hepatitis C infection. Tell your doctor if you're being treated with this medicine.

Some medicines can affect how RUKOBIA works, reducing its effectiveness, causing possible resistance or making it more likely that you will have side effects. RUKOBIA may also affect how these medicines work.

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

- amiodarone, disopyramide, dofetilide, ibutilide, procainamide, quinidine, or sotalol, used to treat heart conditions
- statins (rosuvastatin, atorvastatin, pitavastatin, simvastatin or fluvastatin), used to lower cholesterol levels
- ethinyl estradiol, used for birth control.

Tell your doctor or pharmacist if you are taking any of these. Your doctor may decide to adjust your dose or that you need extra check-ups.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

## **4. How do I use RUKOBIA?**

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

They may differ from the information contained in this leaflet.

### **How much to take**

- The usual dose of RUKOBIA is one 600 mg tablet, twice a day.
- Follow the instructions provided and continue taking your medicine for as long as your doctor tells you.

## **How to take RUKOBIA**

- RUKOBIA should be swallowed whole, with some liquid. Don't chew, crush or split the tablets - if you do, there is a danger you could overdose, because the medicine may be released into your body too quickly.
- You can take RUKOBIA with or without food.

## **If you forget to use RUKOBIA**

RUKOBIA should be used regularly at the same times each day. If you miss your dose at the usual time, take it as soon as you remember. Then continue your treatment as before.

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 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 use too much RUKOBIA**

If you think that you have used too much RUKOBIA, 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 using RUKOBIA?**

### **Things you should do**

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

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.

## **You will need regular blood tests**

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

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

RUKOBIA 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 RUKOBIA 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 RUKOBIA 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). RUKOBIA 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

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

## **Things you should not do**

- Do not take RUKOBIA 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.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how RUKOBIA affects you.**

RUKOBIA 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.

## **Looking after your medicine**

- 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 RUKOBIA 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 young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## 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 printed on the pack or if the packaging is torn or shows signs of tampering.

## 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.

### Less serious side effects

Less serious side effects	What to do
<p><b>Very common side effects</b></p> <p>These may affect more than 1 in 10 people:</p> <p><b>Gastrointestinal:</b></p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• feeling sick (nausea)</li> <li>• diarrhoea</li> <li>• being sick (vomiting)</li> <li>• stomach pain (abdominal pain)</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>• headache</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>• rash</li> </ul> <p><b>Common side effects</b></p> <p>These may affect up to 1 in 10 people:</p> <p><b>Gastrointestinal:</b></p> <ul style="list-style-type: none"> <li>• indigestion (dyspepsia)</li> </ul> <p><b>General:</b></p> <ul style="list-style-type: none"> <li>• lack of energy (fatigue)</li> <li>• feeling weak (asthenia)</li> <li>• feeling drowsy (somnolence)</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>• dizziness</li> <li>• taste disturbance (dysgeusia)</li> </ul> <p><b>Psychiatric:</b></p>	

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• difficulty in sleeping (insomnia)</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>• itching (pruritus)</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>• disturbance in heart rhythm (electrocardiogram QT prolonged)</li> </ul> <p><b>Musculoskeletal:</b></p> <ul style="list-style-type: none"> <li>• muscle pain (myalgia)</li> </ul> <p><b>From blood tests:</b></p> <ul style="list-style-type: none"> <li>• increase in the level of enzymes produced in the muscles (creatine phosphokinase, an indicator of muscle damage)</li> <li>• increase in a kidney function blood test result (creatinine, an indicator</li> </ul>	<p><b>Call your doctor straight away if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<p>of how well your kidneys are working)</p> <ul style="list-style-type: none"> <li>• increase in the level of enzymes produced in the liver (transaminases increased, an indicator of liver damage)</li> </ul>	

**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 RUKOBIA contains

<b>Active ingredient (main ingredient)</b>	<b>Fostemsavir 600mg (as fostemsavir trometamol )</b>
<b>Other ingredients (inactive ingredients)</b>	colloidal anhydrous silica hyprolose hypromellose magnesium stearate OPADRY II complete film coating system 85F170022 BEIGE

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

## What RUKOBIA looks like

RUKOBIA tablets are beige, film-coated, biconvex, oval tablets which may have a slight odour (vinegar-like), debossed with 'SV 1V7' on one side. (AUST R 337863).

## Who distributes RUKOBIA

RUKOBIA is supplied in Australia by:

ViiV Healthcare Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, VIC 3067

Australia

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