

RUKOBIA
Patient Information Leaflet

SCHEDULING STATUS:

S4

RUKOBIA
(600 mg fostemsavir)
Prolonged-release tablet
Sugar-free

Read all this leaflet carefully before you start taking RUKOBIA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- RUKOBIA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What RUKOBIA is and what it is used for:

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

RUKOBIA contains the inactive ingredient fostemsavir which is changed in the body to the active form of the medicine, temsavir. RUKOBIA is a type of medicine known as an antiretroviral. 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 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 antiretroviral medicines (*combination therapy*), to treat HIV infection in adults who have had difficulty in controlling their HIV with many other antiretroviral medicines.

2. What you need to know before you take RUKOBIA:

Do not take RUKOBIA:

- if you are hypersensitive (allergic) to fostemsavir or any of the other ingredients of RUKOBIA (listed in section 6)
 - if you are taking any of these medicines:
 - carbamazepine, or phenytoin (also known as anticonvulsants used 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*) (an herbal product).
- ➔ **If you think any of these apply to you, don't take RUKOBIA** until you have checked with your doctor.

Warnings and precautions:

Take special care with RUKOBIA:

- RUKOBIA should not be taken by children under the age of 18 years.

Before you take RUKOBIA your doctor needs to know:

- if you have or had a heart problem, or if you notice any unusual changes in your heart-beat (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 any of the above applies to you. You may need extra check-ups, including blood tests, while you're taking your medication.

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 touch 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). You can still pass on HIV when taking RUKOBIA, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

Conditions you need to look out for:

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

- ***Symptoms of infection and inflammation:*** See '*Conditions you need to look out for*' in Section 4.

Other medicines and RUKOBIA:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary and traditional medicines.)

Don't take RUKOBIA with the following medicines:

- 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*) (an herbal product).

This medicine is not recommended with RUKOBIA:

- elbasvir/grazoprevir, to treat hepatitis C infection.
 - ➔ Tell your doctor if you are being treated with this medicine.

Some medicines can affect how RUKOBIA works or make it more likely that you will have side effects.

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

- 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.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking RUKOBIA.

You should not breastfeed, as RUKOBIA is excreted in breast milk

Driving and using machines:

RUKOBIA 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.

It is not always possible to predict to what extent RUKOBIA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in driving or operating machinery/equipment, until they are aware of the measure to which RUKOBIA affects them.

3. How to take RUKOBIA:

Do not share medicines prescribed for you with any other person.

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

The usual **adult** 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 - 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.

You will need regular blood tests:

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

If you take more RUKOBIA than you should:

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

If you forget to take RUKOBIA:

Don't take a double dose to make up for a missed dose. Just take it as soon as you remember.

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

If you stop taking RUKOBIA:

To control your HIV infection and to stop your illness from getting worse, take RUKOBIA for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects:

RUKOBIA can have side effects.

Not all side effects reported for RUKOBIA are included in leaflet. Should your general health worsen or if you experience any untoward effects while taking RUKOBIA, please consult your healthcare provider for advice.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of RUKOBIA 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 RUKOBIA.

If any of the following happens, stop taking RUKOBIA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

→ These are all very serious side effects. If you have them, you may have had a serious reaction to RUKOBIA.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- feeling sick (*nausea*)
- diarrhoea
- being sick (*vomiting*)
- stomach pain (*abdominal pain*)
- rash
- indigestion (*dyspepsia*)
- lack of energy (*fatigue*)
- feeling weak (*asthenia*)
- symptoms of infection or of autoimmune disorders (*Immune Reconstitution Inflammatory Syndrome, see 'Conditions you need to look out for'*)
- disturbance in heart rhythm (*electrocardiogram QT prolonged*)
- muscle pain (*myalgia*)
- feeling drowsy (*somnolence*)
- dizziness
- taste disturbance (*dysgeusia*)
- numbness, tingling or weakness of the arms and legs (*peripheral neuropathy*)
- difficulty in sleeping (*insomnia*)
- itching (*pruritus*).

Frequent side effects that may show up in blood tests are:

- increase in the level of enzymes produced in the muscles (*creatine phosphokinase, an indicator of muscle damage*)

- increase in a kidney function blood test result (*creatinine*, an indicator of how well your kidneys are working)
- increase in the level of enzymes produced in the liver (*transaminases increased*, an indicator of liver damage).

Other side effects that may show up in blood tests:

- increase in *bilirubin* (a substance produced by the liver) in the blood.
 - ➔ 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.

Conditions you need to look out for:

Some other conditions may develop during HIV treatment.

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 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 side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the '**6.04 Adverse Drug Reaction Reporting Form**,' found online under SAHPRA publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of RUKOBIA.

5. How to store RUKOBIA:

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not use after the expiry date on the label or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of the pack and other information:

What RUKOBIA contains:

The active substance is fostemsavir.

Each tablet contains 600 mg fostemsavir (as fostemsavir tromethamine).

Sugar-free.

The other ingredients are:

Tablet core: Hydroxypropylcellulose, hypromellose, colloidal anhydrous silica, magnesium stearate.

Tablet coating: Polyvinyl alcohol, titanium dioxide (E171), macrogol 335, talc, iron oxide yellow (E172), iron oxide red (E172).

What RUKOBIA looks like and contents of the pack:

Beige, film-coated, biconvex, oval tablets which may have a slight odour (vinegar-like), debossed with 'SV 1V7' on one side.

RUKOBIA tablets are supplied in white, high-density polyethylene (HDPE) bottles with polypropylene child resistant closures that include a polyethylene faced induction heat seal liner. Each bottle contains 60 film-coated tablets. Each bottle is packed into a cardboard carton.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

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This leaflet was last revised in:

23 August 2022

Registration Number:

54/20.2.8/0887

GDSv3