

Package leaflet: Information for the patient

Rukobia 600 mg prolonged-release tablets fostemsavir

▼ 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 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
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1. What Rukobia is and what it is used for

Rukobia contains fostemsavir and is a type of HIV medicine (anti-retroviral) known as an *attachment inhibitor* (AI). It works by attaching to the virus and then blocking it from entering your blood cells.

Rukobia is used with other anti-retroviral medicines (*combination therapy*), to treat HIV infection in adults with limited treatment options (other anti-retroviral medicines are not sufficiently effective or are not suitable).

Rukobia does not cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level. Given HIV reduces the number of CD4 cells in your body, keeping HIV at a low level also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cell that are important in helping your body fight infection.

2. What you need to know before you take Rukobia

Do not take Rukobia

- if you are **allergic to fostemsavir** or to any of the other ingredients of this medicine (listed in Section 6)
- if you are taking any of these medicines:
 - **carbamazepine**, or **phenytoin** (used to treat **epilepsy** and prevent seizures (fits))
 - **mitotane** (to treat several types of **cancer**)

- **enzalutamide** (to treat **prostate cancer**)
- **rifampicin** (to treat some **bacterial infections** such as **tuberculosis**)
- medicines that contain **St John's wort** (*Hypericum perforatum*) (a herbal product for **depression**).

➔ **If you think any of these apply to you, do not take Rukobia** until you have checked with your doctor.

Warnings and precautions

Conditions you need to look out for

Some people taking medicines for HIV infection develop other conditions, which can be serious. These include:

- infections and inflammation
- joint pain, stiffness and bone problems

You need to know about important signs and symptoms to look out for while you are taking Rukobia.

➔ See Section 4 of this leaflet.

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 hepatitis C.

➔ **Talk to your doctor** if this applies to you. You may need extra check-ups, including blood tests, while you are taking your medicines.

You will need regular blood tests

For as long as you are 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.

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 do not 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 this medicine, although effective anti-retroviral therapy lowers the risk. Discuss with your doctor the precautions you need to take to avoid infecting other people.

Children and adolescents

Rukobia is not recommended for people aged under 18 years because it has not been studied in this age group.

Other medicines and Rukobia

Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking new ones.

Rukobia must not be taken with some other medicines

Do not take Rukobia if you are taking any of these medicines:

- **carbamazepine**, or **phenytoin**, 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 for **depression**).

This medicine is not recommended with Rukobia:

- elbasvir/grazoprevir, to treat **hepatitis C infection**.

➔ **Tell your doctor or pharmacist** if you are being treated with this medicine.

Some medicines can affect how Rukobia works

Or they can make it more likely that you will have side effects. Rukobia can also affect how some other medicines work.

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

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

➔ **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

If you are **pregnant**, or **think you could be**, or if you are **planning to have a baby**, **do not take Rukobia** without checking with your doctor. **Your doctor** will discuss with you the benefit and the risk to your baby of taking Rukobia while you're pregnant.

Breast-feeding

Women who are HIV-positive must 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.

➔ **Talk to you doctor immediately**, if you are breast-feeding, or thinking about breast-feeding.

Driving and using machines

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

Do not drive or use machines unless you are sure you are not affected.

3. How to take Rukobia

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

- **The usual dose** of Rukobia is one 600 mg tablet, twice a day.
- **Rukobia should be swallowed whole**, with some liquid. **Do not chew, crush or split the tablets** — if you do, there is a danger the medicine may be released into your body too quickly.
- You can take Rukobia **with or without food**.

If you take more Rukobia than you should

If you take too many tablets of Rukobia **contact your doctor or pharmacist**. If possible, show them the Rukobia pack.

If you forget to take Rukobia

Take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and go back to your regular schedule. **Do not take a double dose** to make up for a missed dose. If you are not sure what to do, **ask your doctor or pharmacist**.

If you stop taking Rukobia

Do not stop Rukobia without checking with your doctor.

To control your HIV infection and to stop your illness getting worse, take Rukobia for as long as your doctor recommends. Do not stop unless your doctor asks 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, but not everybody gets them, **so it is very important to talk to your doctor about any changes in your health**.

Symptoms of infection and inflammation are common (may affect up to 1 in 10 people)

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 mistakenly 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 **pain**
- **joint pain** or **swelling**
- **weakness** that starts in the hands and feet and moves up towards the trunk of the body
- **palpitations** or **tremor**
- **excessive restlessness** and **movement** (*hyperactivity*).

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

- ➔ **Tell your doctor immediately.** Do not take other medicines for the infection without checking with your doctor.

Very common side effects (may affect **more than 1 in 10 people**):

- feeling sick (*nausea*)
- diarrhoea
- being sick (*vomiting*)
- stomach pain (*abdominal pain*)
- headache
- rash.

- ➔ **Talk to your doctor** if you get any side effects.

Common side effects (may affect **up to 1 in 10 people**):

- indigestion (*dyspepsia*)
- lack of energy (*fatigue*)
- disturbance in heart rhythm seen in ECG test (*prolonged QT interval*)
- muscle pain (*myalgia*)
- feeling drowsy (*somnolence*)
- dizziness
- taste disturbance (*dysgeusia*)
- wind
- difficulty sleeping (*insomnia*)
- itching (*pruritus*).

- ➔ **Talk to your doctor** if you get any side effects.

Some side effects may only be seen in your blood tests and may not appear immediately after you start taking Rukobia.

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

- increase in enzymes produced in the muscles (creatine phosphokinase, an indicator of muscle damage)
- increase in creatinine, an indicator of how well your kidneys are working
- increase in enzymes produced in the liver (transaminases, an indicator of liver damage).

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.

Joint pain, stiffness and bone problems

Some people taking combination therapy for HIV develop a condition called *osteonecrosis*. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains in the joints (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:

→ **Tell your doctor.**

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 Rukobia

Keep out of the sight and reach of children.

Do not take Rukobia after the expiry date shown on the pack which is stated after EXP on the carton and bottle.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines in wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. This will help protect the environment.

6. Contents of the pack and other information

What Rukobia contains

- The active substance is fostemsavir. Each tablet contains fostemsavir tromethamine equivalent to 600 mg fostemsavir.
- The other ingredients are hydroxypropylcellulose, hypromellose, colloidal anhydrous silica, magnesium stearate, poly(vinyl alcohol), titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172), iron oxide red (E172).

What Rukobia looks like and contents of the pack

Rukobia 600 mg prolonged-release tablets are beige, oval, biconvex tablets, approximately 19 mm in length, 10 mm in width, and 8 mm in thickness, film-coated, and marked with the code 'SV 1V7' on one side.

Each pack consists of one or three bottles, each containing 60 prolonged-release tablets.

Not all pack sizes may be available in your country.

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	Rukobia
Reference number	PLGB 35728/0058

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

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