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Rukobia (*fostemsavir*)

An overview of Rukobia and why it is authorised in the EU

What is Rukobia and what is it used for?

Rukobia is a medicine used to treat adults infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). Rukobia is given with other HIV medicines when none of the standard combinations work well enough to control the infection because the virus is resistant to them (multi-drug resistant HIV-1).

How is Rukobia used?

Rukobia can only be obtained with a prescription. It should be prescribed by a doctor who is experienced in the treatment of HIV infection.

The medicine is available as prolonged-release tablets, which release the active substance slowly over a few hours. One tablet should be taken twice a day.

For more information about using Rukobia, see the package leaflet or contact your doctor or pharmacist.

How does Rukobia work?

When in the body, the medicine attaches to a protein on the outer envelope of the HIV-1 virus. This prevents the virus from interacting with immune cells called T cells, which are the main target of the HIV-1 virus. By preventing the virus from entering the T cells and reproducing inside them, Rukobia slows down the spread of infection.

Rukobia does not cure HIV-1 infection or AIDS, but it may hold off damage to the immune system and the development of infections and diseases associated with AIDS.

What benefits of Rukobia have been shown in studies?

Rukobia taken with other HIV medicines was shown to be effective at reducing viral load (blood levels of HIV-1 virus) in patients with multi-drug resistant HIV-1.

In a main study involving adults with multi-drug resistant HIV-1, patients were given Rukobia or placebo (a dummy treatment) in addition to their usual HIV medicines. At the start of treatment,

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patients had a viral load of at least 400 copies/ml. After 8 days, 65% of patients who were taking Rukobia had a decrease in the viral load compared with 19% of patients receiving placebo.

After around 22 months taking Rukobia, the viral load had fallen to below 40 copies/ml in 60% of patients taking at least one other HIV medicine that worked and in 37% of patients in whom no other HIV medicines were working.

What are the risks associated with Rukobia?

The most common side effects with Rukobia (which may affect more than 1 in 10 people) are diarrhoea, headache, nausea (feeling sick), rash, belly pain and vomiting.

The most serious side effect (which may affect more than 1 in 100 people) is immune reconstitution inflammatory syndrome (when the immune system starts working again, leading to inflammation and damage to healthy tissue).

Rukobia must not be taken with certain medicines called 'strong CYP3A inducers', including epilepsy medicines carbamazepine and phenytoin, cancer medicines mitotane and enzalutamide, the antibiotic medicine rifampicin and the herbal medicine St John's wort (*Hypericum perforatum*).

For the full list of side effects and restrictions with Rukobia, see the package leaflet.

Why is Rukobia authorised in the EU?

Rukobia suppressed the HIV-1 virus in patients for whom other HIV medicines were not working and no major safety concerns were identified. The European Medicines Agency therefore decided that Rukobia's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Rukobia?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rukobia have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Rukobia are continuously monitored. Side effects reported with Rukobia are carefully evaluated and any necessary action taken to protect patients.

Other information about Rukobia

Rukobia received a marketing authorisation valid throughout the EU on 4 February 2021.

Further information on Rukobia can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rukobia.

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