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Rukobia® (active substance: fostemsavir)

First authorisation in Switzerland: 28 September 2021

Medicinal product (film-coated tablets) for the treatment of infections with type-1 human immunodeficiency virus (HIV-1) in adults

About the medicinal product

Rukobia, containing the active substance fostemsavir, is a medicinal product for HIV treatment in adults infected with type-1 human immunodeficiency virus (HIV-1). This is a life-threatening disease and causes acquired immunodeficiency syndrome (AIDS).

Rukobia is used in combination with other antiretrovirals[1] to treat HIV-1 infection in adults whose current antiviral therapy cannot be continued due to resistance, i.e. they are infected with multi-drug resistant HIV-1.

These patients represent a subgroup of patients living with HIV.

Rukobia helps control, but cannot cure, the HIV infection.

Mode of action

The active substance of Rukobia, fostemsavir, is a "prodrug", with no antiviral activity of its own. Fostemsavir is only converted into the active substance temsavir in the body.

Rukobia belongs to a group of medicinal products known as attachment inhibitors. Temsavir acts by binding to the virus, thereby preventing the HI virus from binding to blood cells and subsequent infection.

Use

Rukobia, containing the active substance fostemsavir, is a prescription-only medicine.

Rukobia is a film-coated tablet available at the dosage strength of 600 mg. It is a sustained-release tablet, which releases the active substance slowly over several hours. The usual dose is one tablet twice a day.
Rukobia should be taken whole, unchewed, with liquid. The tablet should not be chewed, crushed or split, since faster release

[1] Antiretroviral: This type of medicinal product targets retroviruses whose genetic material is contained in RNA. The HI virus is a retrovirus.

of the medicinal product in the body creates the risk of an overdose. Rukobia does not need to be taken with a meal.

Efficacy

The efficacy of Rukobia in adults infected with HIV who had previously been intensively treated was investigated in the BRIGHTE study (205888) with 371 patients.

The study investigated the efficacy of Rukobia versus placebo (dummy drug) in the majority of participants. The medicinal product or placebo was combined with another antiretroviral treatment.

In addition, the efficacy of Rukobia was investigated in a third, smaller group of patients for whom there are no treatment options. The findings of this efficacy investigation are considered to be supportive.

The study found that patients who received Rukobia in addition to another antiretroviral treatment had a lower viral load (reduction in HIV-1 virus in the blood) than study participants who received the placebo instead of Rukobia.

Precautions, undesirable effects & risks

Rukobia must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most frequent adverse effects are nausea, diarrhoea, vomiting, stomach pain, headache and rash.

All precautions, risks and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Treatment of patients infected with multi-drug resistant HIV is complex and challenging. They have only limited treatment options. There is a medical need for new treatment options for this subgroup of HIV patients.
Rukobia offers a new mode of action without triggering resistance to current antiretrovirals.

The pivotal study shows that patients who received Rukobia in addition to another antiretroviral treatment were able to keep the disease under control over a period of 96 weeks.

Taking all the risks and precautions into account, and based on the available data, the benefits of Rukobia outweigh the risks. Swissmedic has therefore approved the medicinal product Rukobia, containing the active substance fostemsavir, in Switzerland for the treatment of heavily treatment-experienced patients infected with multi-drug resistant HIV.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Rukobia®

Information for patients (package leaflet): Information for patients Rukobia®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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