10 December 2020
EMA/CHMP/613669/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rukobia

fostemsavir

On 10 December 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rukobia, intended for the treatment of multidrug resistant HIV-1 infection. The applicant for this medicinal product is ViiV Healthcare B.V.

Rukobia will be available as 600 mg prolonged-release tablets. The active substance of Rukobia is fostemsavir, an antiviral for systemic use (ATC code: J05AX29). It selectively inhibits the interaction between HIV and cellular CD4 receptors, thereby preventing viral entry into the host cells.

The benefits with Rukobia are its ability to reduce the viral load and keep it at a low level. Given that HIV reduces the number of CD4 cells, keeping HIV at a low level also increases the CD4 cell count. The most common side effects are feeling sick (nausea), diarrhoea, vomiting, abdominal pain, headache and rash.

The full indication is:

> Rukobia, in combination with other antiretrovirals, is indicated for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen.

It is proposed that Rukobia be prescribed by physicians experienced in the management of HIV infection.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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