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Withdrawal of application for the marketing authorisation of Raltegravir Viatris (raltegravir)

The company Viatris withdrew its application for a marketing authorisation of Raltegravir Viatris for the treatment of human immunodeficiency virus type 1 (HIV-1) infection.

The company withdrew the application on 22 February 2023.

What is Raltegravir Viatris and what was it intended to be used for?

Raltegravir Viatris was developed as an antiviral medicine to treat human immunodeficiency virus type 1 (HIV-1) infection in adults and children (weighing at least 40 kg). HIV-1 is a virus that causes acquired immune deficiency syndrome (AIDS). Raltegravir Viatris was to be used together with other antiviral medicines.

Raltegravir Viatris contains the active substance raltegravir and was to be available as tablets to be taken by mouth.

Raltegravir Viatris was developed as a 'generic medicine'. This means that it contained the same active substance as an authorised 'reference medicine', in this case Isentress, and was intended to work in the same way. For more information on generic medicines, see the question-and-answer document here.

How does Raltegravir Viatris work?

The active substance in Raltegravir Viatris, raltegravir, is an integrase inhibitor. It blocks an enzyme called integrase, which is involved in the reproduction of HIV. When the enzyme is blocked, the virus cannot reproduce normally, slowing down the spread of infection. Raltegravir Viatris, taken in combination with other HIV medicines, was expected to reduce the amount of HIV in the blood and keep it at a low level. It does not cure HIV infection or AIDS, but it holds off the damage to the immune system and the development of infections and diseases associated with AIDS.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What did the company present to support its application?

Studies on the benefits and risks of the active substance are not needed for a generic medicine because they have already been carried out with the reference medicine. As for every medicine, the company provided studies on the quality of Raltegravir Viatris. It also provided studies to investigate whether Raltegravir Viatris is 'bioequivalent' to the reference medicine Isentress. Two medicines are bioequivalent when they produce the same level of the active substance in the body and are therefore expected to have the same effect.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Raltegravir Viatris could not have been authorised for the treatment of HIV-1 infection.

The Agency considered that bioequivalence with the reference medicine has not been demonstrated as the study results showed differences in the absorption rate (the rate at which the medicine is absorbed after administration). The Agency also had concerns about the data provided on the quality of the medicine which could not guarantee that future batches of Raltegravir Viatris would be of adequate quality.

Therefore, at the time of the withdrawal, the Agency's opinion was that the medicine could not have been authorised based on the data from the company.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it withdrew its application as EMA considered that the data provided did not allow drawing conclusions on the bioequivalence of the product.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.