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Rekambys (*rilpivirine*)

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

What is Rekambys and what is it used for?

Rekambys is used together with another medicine called cabotegravir to treat adults and adolescents aged 12 years and older infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). It is used when the infection is under control with other HIV medicines. Adolescents must weigh at least 35 kg to take Rekambys.

Rekambys contains the active substance rilpivirine.

How is Rekambys used?

Rekambys is given by injection into a muscle of the hip or buttock. After being injected, the active substance in Rekambys is released slowly over a few weeks into the bloodstream.

Before starting treatment, the doctor ensures that the patient agrees to keep to the schedule of injections, because this is important to keep the virus under control and there is a risk that levels of the virus could increase or the virus could become resistant to treatment if doses are missed.

Rilpivirine and cabotegravir tablets are taken daily by mouth for one month, after which Rekambys and cabotegravir injections are given monthly or every 2 months.

If treatment with Rekambys is stopped, another treatment to suppress the virus must be started to minimise the risk that the virus could become resistant to treatment.

Rekambys can only be obtained with a prescription and treatment should be started by a doctor who has experience in the management of HIV infection.

For more information about using Rekambys, including the schedule for the injections, see the package leaflet or contact your doctor or pharmacist.

How does Rekambys work?

Rekambys is a type of HIV medicine called a non-nucleoside reverse transcriptase inhibitor (NNRTI). It blocks the activity of reverse transcriptase, an enzyme produced by HIV-1 that allows it to make more viruses in the cells it has infected. By blocking this enzyme, Rekambys, taken in combination with cabotegravir, reduces the amount of HIV in the blood and keeps it at a low level. Rekambys does not

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cure HIV infection or AIDS, but it can hold off damage to the immune system and the development of infections and diseases associated with AIDS.

What benefits of Rekambys have been shown in studies?

Rekambys, taken together with cabotegravir, was as effective as other HIV medicines in maintaining the HIV-1 level in the blood (viral load) below a defined level (less than 50 HIV-1 RNA copies/ml) in 3 main studies involving adults with HIV-1 infection. The studies involved patients who had not taken HIV medicines before or who had been taking these medicines for at least 6 months.

In the first two studies, patients were treated with Rekambys and cabotegravir or with combinations of other medicines. After 48 weeks of treatment, the HIV-1 level was above the limit in 1.9% of patients (11 out of 591) taking monthly injections of Rekambys and cabotegravir and in 1.7% of patients (10 out of 591) taking other medicines.

The third study showed that injections of Rekambys and cabotegravir given monthly or every 2 months were similarly effective. After 48 weeks of treatment, the HIV-1 level was above the limit in 1.7% of patients (9 out of 522) given injections every 2 months, compared with 1% of patients (5 out of 523) who had monthly injections.

A further study showed that giving Rekambys to adolescents aged 12 years and older and weighing at least 35 kg resulted in blood levels of the active substance similar to those seen in adults. Therefore, the medicine is expected to have similar effects in adolescents.

What are the risks associated with Rekambys?

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

The most common side effects with Rekambys and cabotegravir monthly injections (which may affect more than 1 in 10 people) include injection site reactions, headache and fever.

Rekambys must not be used with the following medicines as they may lead to reduced blood levels of the medicine, reducing its effectiveness:

- carbamazepine, oxcarbazepine, phenobarbital and phenytoin (medicines for epilepsy);
- rifabutin, rifampicin and rifapentine (antibiotics);
- systemic dexamethasone (a steroid anti-inflammatory and immunosuppressant medicine), except when used as a single dose treatment;
- St John’s wort (a herbal antidepressant medicine).

Why is Rekambys authorised in the EU?

Injections every month or every 2 months may be more convenient for patients than taking medicines every day. Studies showed that the injections were as effective at keeping the virus level low as other standard medicines. It is important that patients keep to the schedule of injections to avoid the virus becoming resistant to treatment, and further studies will determine whether this is happening while the medicine is on the market. The European Medicines Agency decided that Rekambys’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 Rekambys?

The company that markets Rekambys will carry out 2 studies on how the medicine is used and its effectiveness. The outcomes for patients who switch to other treatments after taking Rekambys will also be studied.

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

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

Other information about Rekambys

Rekambys received a marketing authorisation valid throughout the EU on 17 December 2020.

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

This overview was last updated in 01-2025.