EMA/365082/2024
EMEA/H/C/002264

Edurant (*rilpivirine*)

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

What is Edurant and what is it used for?

Edurant is an HIV medicine belonging to the class called non-nucleoside reverse transcriptase inhibitors (NNRTI). It is used in combination with other HIV medicines to treat human immunodeficiency virus type 1 (HIV-1) infection in adults and children from 2 years of age and weighing at least 14 kg. HIV-1 is a virus that causes acquired immune deficiency syndrome (AIDS).

Edurant is only used in people who have an infection with HIV-1 that has no mutations known to cause resistance to NNRTI medicines and who have HIV levels in the blood (viral load) of no more than 100,000 HIV-1 RNA copies/ml.

Edurant contains the active substance rilpivirine.

How is Edurant used?

Edurant can only be obtained with a prescription and treatment should be started by a doctor experienced in treating HIV infection.

Edurant is available as tablets to be swallowed whole and as dispersible tablets, and is to be taken once a day with a meal. Dispersible tablets should be dispersed in water before being taken and are for children weighing at least 14 kg but less than 25 kg; the dose depends on the child's weight.

The doctor will increase the dose of Edurant if the medicine is being taken together with rifabutin (an antibiotic to treat certain bacterial infections).

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

How does Edurant work?

The active substance in Edurant, rilpivirine, blocks the activity of reverse transcriptase, an enzyme (protein) produced by HIV-1 that allows it to make more viruses in the cells it has infected. By blocking this enzyme, Edurant, taken in combination with other HIV medicines, reduces the amount of HIV in the blood and keeps it at a low level.

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 benefits of Edurant have been shown in studies?

Adults

Edurant was investigated in two main studies in 1,368 previously untreated adults with HIV-1 infection. In the first study, Edurant was compared with another NNRTI medicine called efavirenz, when both medicines were given in combination with other HIV medicines called tenofovir disoproxil and emtricitabine. In the second study, Edurant was compared with efavirenz, when both medicines were given in combination with tenofovir disoproxil and emtricitabine or two other nucleoside or nucleotide reverse transcriptase inhibitors (other HIV-1 medicines).

In both studies, the main measure of effectiveness was based on the reduction in viral load. Patients who reached a viral load of less than 50 HIV-1 RNA copies/ml after 48 weeks of treatment were considered to have responded to treatment. The studies found that, when used in combination with other antiretroviral medicines, Edurant was as effective as the comparator medicine at reducing the level of HIV-1 in adults. The results from the two studies showed that 84% of patients taking Edurant responded to treatment after one year, compared with 82% of patients taking efavirenz.

Children

Edurant was investigated in a study involving 36 previously untreated adolescents (between 12 and 18 years old) with HIV-1 infection and 18 previously untreated children aged 6 to 11, weighing at least 17 kg and with HIV-1 infection. Edurant was given in combination with other HIV medicines and was not compared with another treatment. The study found that Edurant was effective in children and adolescents, with around 72% of patients responding to treatment (viral load of less than 50 HIV-1 RNA copies/ml) after 48 weeks.

Another study involved 26 children aged 2 to 11, weighing at least 10 kg and with a viral load of less than 50 HIV-1 RNA copies/ml (virally supressed). In this study, Edurant was given with other HIV medicines and was not compared with another treatment. After 48 weeks the viral load remained suppressed in all children.

Data also showed that blood levels of Edurant in children weighing at least 14 kg were similar to those seen in adults and adolescents and its effectiveness is therefore expected to be similar in these children.

What are the risks associated with Edurant?

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

The most common side effects with Edurant (which may affect more than 1 in 10 people) include headache, insomnia, dizziness, nausea (feeling sick), and increased levels of total cholesterol, low-density lipoprotein (LDL) cholesterol, pancreatic amylase (an enzyme produced in the pancreas that breaks down starch into sugars) and transaminases (liver enzymes).

Edurant must not be used with the following medicines as they may lead to reduced blood levels of rilpivirine and thereby reduce the effectiveness of Edurant:

- carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines for seizures);
- rifampicin, rifapentine (antibiotics);
- omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole (proton pump inhibitors for reducing stomach acid);

- 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 Edurant authorised in the EU?

Edurant, in combination with other HIV medicines, was shown to be as effective as the NNRTI most used at the time of approval in the first-line treatment of adults with HIV-1 infection. The European Medicines Agency noted that Edurant causes fewer side effects than this NNRTI in the early stages of treatment and only needs to be taken once a day. Edurant has also been shown to be effective in children 2 to 18 years of age and weighing at least 14 kg.

The Agency also noted that HIV-1 may develop resistance to rilpivirine in patients with a high viral load (above 100,000 HIV-1 RNA copies/ml). Therefore, the Agency considered that the benefits of Edurant outweigh its risks in people with an HIV-1 viral load below 100,000 copies/ml and it can be authorised in the EU for use in this group of people.

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

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

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

Other information about Edurant

Edurant received a marketing authorisation throughout the EU on 28 November 2011.

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

This overview was last updated in MM-2024.