

EMA/752608/2015 EMEA/H/C/002264

#### **EPAR** summary for the public

## **Edurant**

## rilpivirine

This is a summary of the European public assessment report (EPAR) for Edurant. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Edurant.

#### What is Edurant?

Edurant is a medicine that contains the active substance rilpivirine. It is available as tablets (25 mg).

#### What is Edurant used for?

Edurant is used in combination with other antiviral medicines to treat adults and adolescents from the age of 12 years who are infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). It is only used in patients who have not received anti-HIV treatment before and who have HIV levels in the blood (viral load) of no more than 100,000 HIV-1 RNA copies/ml.

The medicine can only be obtained with a prescription.

#### How is Edurant used?

Treatment with Edurant should be started by a doctor experienced in treating HIV infection. The recommended dose of Edurant is one tablet once a day. If Edurant is given together with rifabutin, the doctor should increase the dose of Edurant to two tablets once a day during rifabutin treatment. Edurant must be taken with a meal.

#### How does Edurant work?

Edurant is an antiviral medicine. The active substance in Edurant, rilpivirine, is 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, Edurant, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Edurant does not cure HIV infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

#### How has Edurant been studied?

Edurant was investigated in two main studies in 1,368 previously untreated adult patients infected with HIV-1. In the first study, Edurant was compared with another NNRTI called efavirenz, when both medicines were given in combination with a fixed regimen of antiviral medicines consisting of tenofovir disoproxil and emtricitabine. In the second study, Edurant was compared with efavirenz, when both medicines were given in combination with a fixed regimen of antiviral medicines consisting of tenofovir disoproxil and emtricitabine or two other nucleoside or nucleotide reverse transcriptase inhibitors. Edurant was also investigated in another study in 36 previously untreated adolescents (between 12 and 18 years old) infected with HIV-1. Edurant was given in combination with a fixed regimen of antiviral medicines and was not compared with another treatment.

In all studies, the main measure of effectiveness was based on the reduction in viral load. Patients who attained a viral load of less than 50 HIV-1 RNA copies/ml after 48 weeks of treatment were considered to have responded to treatment.

### What benefit has Edurant shown during the studies?

In adults, Edurant in combination with other antiretroviral medicines was as effective as the comparator medicine at reducing the level of HIV-1 in the patients' blood. Taking the two studies into account, 84% of patients taking Edurant responded to treatment after one year, compared with 82% of patients taking efavirenz. Edurant was also effective in adolescents, with around 72% of patients responding to treatment after 48 weeks.

#### What is the risk associated with Edurant?

The most frequent side effects with Edurant (seen in more than 1 patient in 10) are 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). For the full list of all side effects reported with Edurant, see the package leaflet.

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 fits);
- 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).

For the full list of restrictions, see the package leaflet.

## Why has Edurant been approved?

The CHMP concluded that Edurant, in combination with other antiretroviral medicines, was as effective as the main NNRTI currently used in the first-line treatment of adult patients infected with HIV-1.In addition, Edurant has also been shown to be effective in children aged 12 to 18 years of age. The Committee noted that Edurant causes fewer side effects in the early stages of treatment and offers the benefit of being taken as one tablet once per day. However, the CHMP noted that there was some risk of HIV-1 developing resistance to rilpivirine and that this risk appeared to be lower in patients with a lower viral load. Therefore, the CHMP considered that the benefits of Edurant outweigh its risks in patients with a low HIV-1 viral load, and recommended that it be granted marketing authorisation for this group of patients.

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

A risk management plan has been developed to ensure that Edurant is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Edurant, including the appropriate precautions to be followed by healthcare professionals and patients.

#### Other information about Edurant

The European Commission granted a marketing authorisation valid throughout the European Union for Edurant on 28 November 2011.

The full EPAR for Edurant can be found on the Agency's website: <a href="mailto:ema.europa.eu/Find medicine/Human">ema.europa.eu/Find medicine/Human</a> medicines/European Public Assessment Reports. For more information about treatment with Edurant, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2015.