EMA/170273/2020
EMEA/H/C/000900

Intelence (*etravirine*)

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

What is Intelence and what is it used for?

Intelence is a medicine for treating human immunodeficiency virus type 1 (HIV-1) in adults and children from 2 years of age. HIV-1 causes acquired immune deficiency syndrome (AIDS).

Intelence is only used in patients who have been treated for their HIV infection before and it must be used together with other HIV medicines that include a 'boosted protease inhibitor'.

It contains the active substance etravirine.

How is Intelence used?

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

It is available as tablets (25, 100 and 200 mg) to be swallowed whole with a glass of water. Patients who cannot swallow can disperse the tablets in a glass of water and then drink the solution immediately.In adults, the recommended dose of Intelence is 200 mg twice a day after a meal, while in children the dose depends on body weight and ranges from 100 to 200 mg twice a day.

For further information about using Intelence, see the package leaflet or contact your doctor or pharmacist.

How does Intelence work?

The active substance in Intelence, etravirine, is a non-nucleoside reverse transcriptase inhibitor (NNRTI). It blocks the activity of reverse transcriptase, an enzyme produced by HIV that allows the virus to make more copies of itself in the cells it has infected and so spread in the body. By blocking this enzyme, Intelence, taken in combination with other HIV medicines, reduces the amount of HIV in the blood and keeps it at a low level. Intelence does not cure HIV infection, but it holds off damage to the immune system and the development of infections and diseases associated with AIDS.

What benefits of Intelence have been shown in studies?

Studies have shown that Intelence, in combination with other medicines, could reduce the HIV-level (viral load) to low (below 400 copies/ml) or undetectable levels (below 50 copies/ml) in many patients

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with HIV-1 infection. This was considered to show that the virus was no longer able to make new copies of itself in the body (a viral load above 1000 copies/ml indicated that the virus was actively reproducing).

In two main studies in a total of 1,203 adults whose infection had not responded fully to previous treatment, the average viral load was 70,000 copies/ml at the start of treatment. After 24 weeks, 59% of the patients taking Intelence together with other HIV medicines had undetectable levels of HIV, compared with 41% of those taking placebo (a dummy treatment) plus the other HIV medicines. These findings were maintained at 48 weeks.

In a main study of 101 children aged between 6 and 17 years, about half the children had undetectable levels of HIV after 24 weeks of taking Intelence in combination with other medicines, and the proportion of children with undetectable levels of HIV increased slightly after 48 weeks.

Another study involved 20 children aged between 2 and 5 years whose HIV infection had not responded fully to previous treatment. The average viral load was more than 1,000 copies/ml at the start of treatment. After 48 weeks of taking Intelence together with other HIV medicines, 80% of the children had a viral load below 400 copies/ml.

What are the risks associated with Intelence?

The most common side effects with Intelence (which may affect more than 1 in 10 people) are rash, diarrhoea, nausea (feeling sick) and headache.

Intelence must not be used together with elbasvir/grazoprevir, a medicine to treat hepatitis C. For the full list of side effects and restrictions with Intelence, see the package leaflet.

Why is Intelence authorised in the EU?

The European Medicines Agency decided that the benefits of Intelence are greater than its risks and that it can be authorised for use in the EU.

The Agency concluded that Intelence is effective at reducing viral load to very low or undetectable levels in both adults and children and that its side effects are considered manageable.

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

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

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

Other information about Intelence

Intelence received a marketing authorisation valid throughout the EU on 28 August 2008.

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

This overview was last updated in 04-2020.