EMA/134086/2020
EMEA/H/C/004427

Juluca (*dolutegravir / rilpivirine*)

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

What is Juluca and what is it used for?

Juluca is a medicine used to treat adults infected with human immunodeficiency virus-1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS).

Juluca is only used for patients whose levels of HIV-1 in the blood (viral load) have been below 50 copies/ml for at least 6 months on their current HIV treatment combination. It is not suitable for patients in whom any HIV medicine has stopped working or who are infected with HIV that is resistant to medicines that work in the same way as Juluca's active substances.

The active substances in Juluca are dolutegravir and rilpivirine.

How is Juluca used?

Juluca can only be obtained with a prescription and should be prescribed by doctors experienced in managing HIV infection.

The recommended dose is one tablet once daily with a meal. Each tablet contains 50 mg dolutegravir and 25 mg rilpivirine. For more information about using Juluca, see the package leaflet or contact your doctor or pharmacist.

How does Juluca work?

The two active substances in Juluca, dolutegravir and rilpivirine, block the actions of enzymes that the virus needs to make copies of itself in the cells it has infected. Dolutegravir, an integrase inhibitor, blocks an enzyme called integrase, while rilpivirine, a non-nucleoside reverse-transcriptase inhibitor, blocks the activity of another enzyme called reverse transcriptase.

Juluca does not cure HIV infection, but reduces the amount of virus in the body and keeps it at a low level. This holds off damage to the immune system and the development of infections and diseases associated with AIDS.

Both active substances are already available in the EU: dolutegravir has been authorised since 2014 and rilpivirine has been authorised since 2011.

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 Juluca have been shown in studies?

Two main studies found that the combination of dolutegravir and rilpivirine (the active substances in Juluca) was effective at keeping HIV infection under control. The studies involved a total of 1,024 patients whose HIV infection was well controlled for at least 6 months on a combination of three HIV medicines that included a class of HIV medicines called nucleoside (or nucleotide) reverse transcriptase inhibitors (NRTIs). The studies compared the effectiveness of switching to the combination of dolutegravir and rilpivirine with that of remaining on the current combination of HIV medicines. The proportion of patients who had undetectable levels of HIV (below 50 copies/ml) after 48 weeks was the same for patients switching compared with those remaining on the current medicines (95% in both cases).

What are the risks associated with Juluca?

The most common side effects with Juluca (which may affect up to 1 in 10 people) are diarrhoea and headache. The most serious side effects (which may affect up to 1 in 100 people) include allergic reactions that include rash or liver damage.

Juluca must not be used together with certain medicines such as fampridine (a multiple sclerosis medicine, also called dalfampridine), as this may increase the level of such medicines in the body, resulting in serious side effects.

Juluca must also not be used with the following medicines because they may reduce its effectiveness:

- carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines for epilepsy);
- rifampicin, rifapentine (antibiotics);
- omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole (proton pump inhibitors for reducing stomach acid);
- dexamethasone given by mouth or by injection (a steroid anti-inflammatory and immunosuppressant medicine), except when used as a single-dose treatment;
- St John's wort (a herbal medicine used for treating depression).

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

Why is Juluca authorised in the EU?

The European Medicines Agency considered that Juluca's effectiveness was comparable to that of combination treatment with three HIV medicines that include NRTIs. Because Juluca does not contain an NRTI, it is free of long-term side effects caused by NRTIs. The side effects of Juluca are well known and manageable.

The Agency decided that Juluca'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 Juluca?

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

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

Other information about Juluca

Further information on Juluca can be found on the Agency's website: https://www.ema.europa.eu/medicines/human/EPAR/juluca.

This overview was last updated in 03-2020.