EMA/565621/2020
EMEA/H/C/004976

Vocabria (*cabotegravir*)

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

What is Vocabria and what is it used for?

Vocabria is used together with another medicine called rilpivirine to treat adults infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). It is used in adults whose infection is under control with antiretroviral medicines (medicines for HIV).

Vocabria contains the active substance cabotegravir.

How is Vocabria used?

Vocabria is available as tablets to be taken by mouth and as a prolonged-release suspension for injection. 'Prolonged release' means that the active substance is released slowly over a few weeks after being injected. The injection is given into the hip or buttock muscle by a doctor or nurse.

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.

Cabotegravir and rilpivirine tablets are taken daily by mouth for one month, after which Vocabria and rilpivirine injections are given monthly or every 2 months.

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

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

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

How does Vocabria work?

Vocabria is an integrase inhibitor. This is a medicine that blocks an enzyme called integrase that the virus needs to make new copies of itself in the body. By blocking this enzyme, Vocabria, taken together with rilpivirine, reduces the amount of HIV in the blood and keeps it at a low level. Vocabria

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does not 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 Vocabria have been shown in studies?

Vocabria, taken together with rilpivirine, was as effective as other HIV medicines in maintaining 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 patients 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 two studies, patients were treated with Vocabria and rilpivirine or with combinations of other medicines. After 48 weeks, the HIV-1 level was above the limit in 1.9% of patients (11 out of 591) taking monthly injections of Vocabria and rilpivirine and in 1.7% of patients (10 out of 591) taking other medicines.

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

What are the risks associated with Vocabria?

The most common side effects with Vocabria (which may affect more than 1 in 10 people) are injection site reactions, headache and fever.

Vocabria must not be used with carbamazepine, oxcarbazepine, phenobarbital, phenytoin (medicines for epilepsy) or with rifampicin, rifapentine (antibiotics), as these medicines may lead to reduced blood levels of the medicine, reducing its effectiveness.

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

Why is Vocabria authorised in the EU?

Vocabria injections monthly or every 2 months may be more convenient for patients than taking medicines every day. Studies showed that the medicine was 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 once the medicine is on the market. The European Medicines Agency decided that Vocabria'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 Vocabria?

The company that markets Vocabria 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 Vocabria will also be studied.

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

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

Other information about Vocabria

Vocabria received a marketing authorisation valid throughout the EU on 17.12.2020.

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

This overview was last updated in 12-2020.