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Vocabria® (active substance: cabotegravir)

First authorisation in Switzerland: 8 October 2021

For the treatment of infections with the human immunodeficiency virus (HIV-1) in adults

About the medicinal product

Vocabria, containing the active substance cabotegravir, is a medicinal product for the treatment of HIV in adults. Infection with type 1 human immunodeficiency virus (HIV-1) is a life-threatening disease.

Vocabria is used in combination with rilpivirine in adults whose infection has been kept under control for more than 6 months with other antiretroviral agents (drugs against HIV). Rilpivirine is also an active substance used for treating HIV. "Under control" means that the HIV viral load measured in the blood as HIV-1 RNA is no higher than 50 copies per ml.

The treatment is administered by a doctor experienced in the management of HIV infection. Vocabria helps control, but cannot cure, the HIV infection.

Mode of action

Vocabria has an antiretroviral action, i.e. it suppresses further replication of the human immunodeficiency virus (HIV). Vocabria is a so-called integrase inhibitor, which blocks an enzyme (protein) called integrase. The virus requires integrase to enable it to manufacture new copies of itself. By blocking this enzyme Vocabria, combined with rilpivirine, lowers the viral load in the blood and keeps it at a low level. Vocabria cannot cure an HIV infection, but it can delay the onset of the resulting complications.

Use

Vocabria, with the active substance cabotegravir, is a prescription-only medicine and is administered in combination with the active substance rilpivirine. The switch to the combination therapy can be made only when the HIV viral load in the blood has already been kept under control by other antiretroviral agents for at least 6 months.

Vocabria is available as a 30 mg film-coated tablet and as a depot injection at the dosages of 400 mg and 600 mg. "Depot" means that the active substance is released slowly

over several weeks after the injection. Vocabria is injected into the hip muscle or gluteal muscle (intramuscularly).

The treatment with Vocabria is divided into three phases. The treatment starts with the oral administration of one film-coated tablet (30 mg) a day for one month (at least 28 days). Then the patient receives an intramuscular depot injection of 600 mg. From the third month, the patient receives a depot injection of 400 mg once a month. The whole treatment is always combined with the administration of rilpivirine.

Efficacy

The efficacy of Vocabria in combination with rilpivirine was demonstrated in three studies. Two of the studies (FLAIR and ATLAS) compared the new depot combination therapy with the established oral standard treatment (daily combined administration of three active substances). The efficacy on the virus concentration in the blood was comparable. The ATLAS-2M study compared the monthly administration of the new depot combination with administration every two months. Although the efficacy of administration every two months was comparable with once-monthly administration, the study did not include a comparison with the standard treatment.

Precautions, undesirable effects & risks

Vocabria must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common (affecting more than one in 10 users, i.e. more than 10%) undesirable effects are reactions at the injection site, nasopharyngitis (simultaneous inflammation of the nose and throat), upper respiratory tract infections and headache.

Vocabria may not be administered together with active substances that lower the cabotegravir levels in the blood, for example carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin or rifampicin, as these can reduce the efficacy of the treatment with Vocabria.

All precautions, risks and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The studies showed that patients who received Vocabria had virus levels in the blood that were just as low as those during conventional oral treatment. However, the monthly depot injection of Vocabria dispenses with the need for daily administration, which can be beneficial for the patient.

Taking all the risks and precautions into account, and based on the available data, the benefits of Vocabria outweigh the risks. Swissmedic has therefore authorised the medicinal product Vocabria, with the active substance cabotegravir, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Vocabria®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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