swissmedic

Summary report on authorisation dated 14 April 2026

Vocabria® (active substance: cabotegravir)

Indication extension in Switzerland: 14 October 2025

Medicinal product for the long-term treatment of HIV-1 infection in adults and adolescents aged 12 years and older and weighing at least 35 kg.

About the medicinal product

Vocabria contains the active substance cabotegravir and is used for the treatment of infection with type 1 human immunodeficiency virus (HIV-1).

HIV-1 can result in a life-threatening illness. About 40 million people worldwide and 17,000 in Switzerland live with HIV.

Vocabria is used in combination with the active substance rilpivirine for the treatment of adults and adolescents aged 12 years and older and weighing at least 35 kg. Their HIV infection must have been kept under control for more than six months with other antiretroviral agents (drugs against HIV). Rilpivirine is also an active substance used for treating HIV. "Under control" means that the virus is no longer detectable in the blood or is only present in very small amounts. The viral load in the blood is measured as HIV-1-RNA and may not exceed 50 copies per millilitre. Nor may the patient have any known or suspected resistance to, or a history of virological failure with, agents of the NNRTI or INI class.

Vocabria was first authorised by Swissmedic on 8 October 2021 for the treatment, in combination with rilpivirine, of HIV-1 infections in adults. This indication extension means that Vocabria can now also be used in adolescents aged 12 years and older and weighing at least 35 kg.

Mode of action

Vocabria has an antiretroviral action, which means that the human immunodeficiency virus (HIV) is less able to replicate in the body. The active substance cabotegravir belongs to the group known as integrase inhibitors. It blocks the viral enzyme integrase, which the virus needs to integrate its genetic material into the genome of human cells and continue to replicate.

By blocking integrase, cabotegravir inhibits the replication of the virus. When combined with rilpivirine, Vocabria 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.

Administration

Vocabria is available as a prolonged-release suspension for injection and is injected into the gluteal muscle. Prolonged-release injection means that the active substance is released slowly from the muscle over several weeks.

The medicinal product is available as an injection in two dosages: 400 mg in a 2 ml vial and 600 mg in a 3 ml vial.

The treatment can start with a short phase in which the active substances are first taken orally as tablets (at the dose of 30 mg). This allows the doctor to check whether the medication is well tolerated by the patients. If so, the tablets are then switched to the injections. Alternatively, the treatment can also start directly with the injections.

The injections are given either once a month or every two months. The choice of treatment regimen is decided jointly by healthcare professionals and the patients. If the treatment is started without a tablet phase, an initial dose is administered on each of the first two appointments. This is followed by the regular injections at the selected intervals.

It is important to attend the planned appointments so that the viral load in the blood remains at a low level.

Efficacy

The efficacy of Vocabria in combination with rilpivirine in adolescents was investigated in the study IMPAACT 2017 (MOCHA).

The participants in this trial were adolescents aged 12 to under 18 years who were already receiving stable HIV treatment and whose viral load in the blood was below the limit of detection.

They initially received the active substances in tablet form for a short period. The treatment was then switched to injections of Vocabria and rilpivirine administered every four or eight weeks.

The study results showed that viral suppression was maintained in most of the adolescents. After 24 weeks, the viral load continued to remain below 50 copies per millilitre of blood in 98.6 % of the participants.

No confirmed virological failures were observed during this period.

Precautions, undesirable effects, & risks

Vocabria must not be used in those who are hypersensitive to the active substance cabotegravir or any of the excipients. Nor may the medicinal product be used at the same time as certain other drugs that significantly affect the breakdown of cabotegravir, including anti-epilepsy agents or certain antibiotics for example, as these can make Vocabria less effective.

In the study for the indication extension, reactions at the injection site were the most common undesirable effects. They occurred in some of the adolescents and mainly manifested as pain, swelling or redness at the injection site. These effects were usually of mild or moderate intensity and subsided on their own after a short time. Only a few adolescents reported more severe reactions.

Other undesirable effects occurred in only a few individuals and were mild in most cases. They included headache, skin rash or gastrointestinal symptoms. Severe undesirable effects were rare and unconnected to Vocabria.

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

Why the medicinal product has been authorised

Adolescents with HIV-1 have had limited access to date to long-acting treatment options. A treatment that does not need to be taken every day can also help adolescents comply with their treatment more consistently.

The MOCHA study showed that adolescents tolerate the treatment well and that Vocabria, combined with rilpivirine, keeps the viral load at a consistently low level. After both 16 and 24 weeks, almost all of the adolescents remained virologically suppressed. Subsequently collected data confirmed these results. Furthermore, no new safety concerns were observed that differ from the findings in adults.

Swissmedic would highlight the importance of complying with the injection schedule, as the risk of developing resistance increases substantially if appointments are missed.

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, containing the active substance cabotegravir, in Switzerland for the treatment of adolescents aged 12 years and older and weighing at least 35 kg.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Vocabria®

Information for patients (package leaflet): Information for patients 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 Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.