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Summary report on authorisation dated 14 April 2025

Transfert de microbiote fécal pour utilisation allogénique CHUV, Rektalsuspension® (active substance: faecal microbiota)

Authorisation in Switzerland: 12 December 2024

Medicinal product for the treatment of multiple recurrent Clostridioides difficile intestinal infections in adults despite prior antibiotic treatment.

About the medicinal product

The medicinal product named "Transfert de microbiote fécal pour utilisation allogénique CHUV, Rektalsuspension" contains the active substance faecal microbiota, which is obtained from the stool of healthy donors. It is used to treat adults with multiple recurrent intestinal infections caused by Clostridioides difficile (formerly known as Clostridium difficile). These patients have already received at least one prior specific antibiotic treatment. Clostridioides difficile is a bacterium that can cause severe and recurrent diarrhoea, particularly if there is an imbalance in the intestinal microbiome as a result of antibiotic treatment(s). Transfert de microbiote fécal pour utilisation allogénique CHUV, Rektalsuspension is administered in the event of a recurrent infection despite prior specific antibiotic treatments.

Mode of action

The active substance in this medicine is faecal microbiota, which is obtained from the bowel of healthy donors. This medicine is used to restore the balance of the intestinal flora in patients with recurrent Clostridioides difficile infections. When the healthy intestinal flora is transferred, it can help displace the harmful bacteria and thereby fight the infection and prevent new infections.

Use

Transfert de microbiote fécal pour utilisation allogénique CHUV, Rektalsuspension is a prescription-only medicine. A rectal suspension is a liquid dosage form that is administered rectally (into the rectum). The liquid contains the active substance in suspended form (finely dispersed and evenly suspended

in the liquid) and is introduced into the bowel by means of an enema.

The medicinal product is supplied as a rectal suspension in a 250 ml bottle, which corresponds to 70 g of faeces. The usual dosage is 50 to 250 ml, depending on the administration route and the patient's clinical situation. A single dose is sufficient in most cases.

If the infection recurs within 8 weeks, or if the procedure is unsuccessful, a second treatment may be needed. The medicinal product is prescribed and supervised exclusively by specialised professionals in the hospital setting. Each administered dose is entered in the CHUV register, and patients are monitored for 5 years.

Efficacy

The efficacy of Transfert de microbiote fécal pour utilisation allogénique CHUV, Rektalsuspension has been investigated in several systematic literature analyses, based in particular on 6 pivotal studies. Most of these studies showed a benefit of the medicinal product in the treatment of multiple recurrent Clostridioides difficile infections compared to antibiotic therapy. However, the data from the studies are heterogeneous since the treatment procedures and patient groups vary widely. Observational data from 86 patients treated at CHUV with the medicinal product, either as hard capsules or as a rectal suspension, support the benefit of the medicine in treating infections described in the literature.

Precautions, undesirable effects, & risks

Transfert de microbiote fécal pour utilisation allogénique CHUV, Rektalsuspension may not be used in patients who have had a serious allergic reaction to any of the constituents or excipients. Patients with severe immunodeficiency or acute intestinal perforation (local perforation of the intestinal wall) should also not receive this treatment. If necessary, treatment with systemic antibiotics must be postponed, as these can cancel the effect of the faecal transplant. In patients with chronic inflammatory bowel disease, the treatment of this disease should be optimised before and after the stool transfer as there is a risk of flare-ups. Common undesirable effects include gastrointestinal symptoms such as diarrhoea, abdominal discomfort, constipation, flatulence and nausea, although these are usually mild to moderate and temporary.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals, which is provided to the patients.

Why the medicinal product has been authorised

There is a high medical need for treatments for patients with multiple recurrent Clostridioides difficile infections, since conventional antibiotics are often not sufficiently effective on their own. Multiple recurrent infections with Clostridioides difficile are difficult to treat and significantly impair patients' quality of life. The currently available published study data suggest that treatment with Transfert de microbiote fécal pour utilisation allogénique CHUV, Rektalsuspension can help prevent a recurrence of the infection. The observational data from patients treated with this medicinal product at CHUV are consistent with the positive results from the literature. Taking all the risks and precautions into account, and based on the available data, the benefits of Transfert de microbiote fécal pour utilisation allogénique CHUV, Rektalsuspension, outweigh the risks. Swissmedic has therefore authorised the medicinal product Transfert de microbiote fécal

pour utilisation allogénique CHUV, Rektalsuspension, containing the active substance faecal microbiota, for the treatment of multiple recurrent Clostridioides difficile infections in adults for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Transfert de microbiote fécal pour utilisation allogénique CHUV, Rektalsuspension ®

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.