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Summary report on authorisation dated 30 January 2026

Alyftrek® (active substances: vanzacaftor, tezacaftor, deutivacaftor)

Authorisation in Switzerland: 15 October 2025

Film-coated tablets for the treatment of patients with cystic fibrosis

About the medicinal product

Alyftrek contains the active substances vanzacaftor, tezacaftor and deutivacaftor. Alyftrek is used for the treatment of patients with cystic fibrosis (CF) aged 6 years and older who possess at least one F508del mutation or another responsive mutation in the CFTR gene.

Cystic fibrosis is a genetic disease caused by a deficiency and/or a dysfunction of the CFTR gene. The CFTR gene codes for a protein used for transporting water and salts. A dysfunction of the CFTR protein can lead, for example, to the formation of thick mucus in the lungs or pancreas.

Mode of action

Alyftrek acts on a protein called CFTR. This protein is damaged in patients with CF as a result of mutations in the CFTR gene. Vanzacaftor and tezacaftor increase the quantity of the CFTR protein at the cell surface, while deutivacaftor improves the function of this protein. This combination can alleviate the symptoms of CF.

Administration

Alyftrek is a prescription-only medicine.

Alyftrek is available as a film-coated tablet in the dose combination of 4 mg/20 mg/50 mg for those weighing less than 40 kg and the dose combination of 10 mg/50 mg/125 mg for those weighing 40 kg or more.

The recommended daily dose is based on body weight and is taken once a day together with a fat-containing meal. Patients aged 6 years and older weighing between 20 kg and 40 kg should take three tablets with the lower dose combination, whereas patients weighing 40 kg or more receive two tablets with the higher dose combination.

The tablets should be taken at the same time each day.

Efficacy

The efficacy of Alyftrek was investigated in two clinical studies (study 121-102 and study 121-103), in which the participants were patients aged 12 years and older with cystic fibrosis. Both studies compared the effects of Alyftrek and ELX/TEZ/IVA (elexacaftor/tezacaftor/ivacaftor). Participants initially received a four-week treatment with ELX/TEZ/IVA before being treated with either Alyftrek or ELX/TEZ/IVA for a total of 52 weeks. In both studies Alyftrek produced results similar to those for ELX/TEZ/IVA on lung function and a greater improvement on the sweat chloride level (SwCl). The studies confirmed the efficacy of Alyftrek in patients with CF and certain CFTR gene mutations.

Precautions, undesirable effects, & risks

Alyftrek may not be used in those who are hypersensitive to one of the active substances or any of the excipients.

The most common undesirable effects (affecting more than 1 in 10 users) are headache, diarrhoea, and influenza.

Elevated liver enzymes and depression were also observed in some patients taking Alyftrek.

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

Cystic fibrosis is a serious inherited disease that has significant effects on the quality of life of sufferers. The current treatment options are limited and do not offer a cure for the disease, but are designed to reduce its symptoms and complications.

The studies showed that those patients who received Alyftrek experienced effects similar to those for ELX/TEZ/IVA on lung function and a greater improvement on the sweat chloride level (SwCl), without producing any additional serious side effects.

Taking all the risks and precautions into account, and based on the available data, the benefits of Alyftrek outweigh the risks. Swissmedic has therefore authorised the medicinal product Alyftrek, containing the active substances vanzacaftor, tezacaftor and deutivacaftor, in Switzerland for the treatment of patients aged 6 years and older with cystic fibrosis.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Alyftrek®

Information for patients (package leaflet): Information for patients Alyftrek®
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.