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Vyndaqel® (active substances: tafamidis and tafamidis meglumine)

First authorisation in Switzerland: 5 March 2020

Medicine for the treatment of transthyretin amyloidosis in adult patients with wild-type or hereditary cardiomyopathy

About the medicine

Vyndaqel is a medicine containing the active substance tafamidis or tafamidis meglumine. It was authorised in Switzerland on 5 March 2020 for the treatment of transthyretin amyloidosis in adult patients with wild-type or hereditary cardiomyopathy. Transthyretin amyloidosis with wild-type or hereditary cardiomyopathy is a rare heart disease in which the function of a blood protein called transthyretin is defective and forms fibres (amyloid). These fibres are deposited between the heart cells and also at other sites in the body. The deposits in the heart are responsible for preventing the heart muscle from working normally, causing it to thicken and stiffen. The heart is then no longer able to contract and expand uniformly and supply the body with sufficient blood.

The difference between the active substances tafamidis and tafamidis meglumine is the inclusion of meglumine. Meglumine is a salt that is used to adjust the size of the capsules.

Mode of action

The medicine Vyndaqel, with the active ingredient tafamidis or tafamidis meglumine, prevents the blood protein (transthyretin) from breaking up and forming fibres (amyloid), which can be deposited between the heart cells, thereby slowing down the progression of the disease.

Use

Vyndaqel should be prescribed only by a doctor with experience in the treatment of patients with amyloidosis or cardiomyopathy. The recommended dose of Vyndaqel is 61 mg tafamidis or 80 mg tafamidis meglumine once daily (administered as 4 x 20 mg capsules). The effect produced by 61 mg of tafamidis is equivalent to that produced by 80 mg of tafamidis meglumine. Tafamidis and tafamidis meglumine are not interchangeable on the basis of dosage strength.

Efficacy

The efficacy of Vyndaqel has been tested in an international study with 441 patients over a period of 30 months. 177 patients received a dummy drug (placebo), 88 patients received 20 mg of tafamidis and 176 patients received 80 mg of tafamidis.

The analysis of the study showed that the patients treated with the active substance tafamidis did not need to be admitted to hospital as frequently due to cardiovascular problems. The mortality rate was also lower in the patients treated with tafamidis, compared to those who received a dummy drug.

After 6 months, a positive effect was noted in the patients treated with tafamidis, based on a walk test and a questionnaire. This positive effect was maintained until the end of the study (month 30).

Precautions, undesirable effects & risks

Vyndaqel may not be used in those who are hypersensitive to the active substance or any of the excipients. The adverse drug reactions in those patients receiving Vyndaqel were comparable with those in patients who received a dummy drug (placebo).

In other studies on other diseases with the active substance tafamidis meglumine, the observed side effects included the following: diarrhoea, urinary tract infection (pain or burning sensation on passing water or a frequent need to urinate), vaginal infection in women, stomach ache or abdominal pain. These findings only apply to the dosage of 80 mg tafamidis meglumine. Findings for 61 mg tafamidis are not available since this dose was not investigated in the study.

Other precautions, undesirable effects and risks are listed in the Information for healthcare professionals and the Patient information (package leaflet). Healthcare professionals can also provide information about these aspects.

Why the medicine has been authorised

The study has shown that Vyndaqel is well tolerated, mortality is reduced and that fewer hospitalisations due to cardiovascular problems are needed. Overall, the benefit-risk assessment for Vyndaqel was positive. Swissmedic has therefore authorised the medicine Vyndaqel with the active substance tafamidis or tafamidis meglumine for use in Switzerland for the above-mentioned indication.

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Vyndaqel®

Information for patients (package leaflet):
Patient information Vyndaqel®

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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