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Enspryng® (active substance: satralizumab)

First authorisation in Switzerland: 13.07.2020

Medicinal product (prefilled syringe) for the treatement of adult and adolescent patients with neuromyelitis optica spectrum disorders who test positive for aquaporin-4 IgG protein

About the medicine

The medicinal product Enspryng, containing the active substance satralizumab, is a medicine available in a prefilled syringe authorised in Switzerland on 13 July 2020.

Enspryng may be used alone or with treatments that lower the body's immune system response.

It has been authorised for the treatment of neuromyelitis optica spectrum disorder in adult and adolescent patients in whom certain proteins, called aquaporin-4 IgG protein, are detected.

Neuromyelitis optica spectrum disorders are rare autoimmune diseases that cause inflammation mainly of the spinal cord and of the optic nerve. Damage from repeated attacks of inflammation in the central nervous system can lead to a wide range of symptoms, such as blindness, loss of sensation, reduction of vision, weakness or paralysis of arms and legs, loss of bladder control, neuropathic pain and fatigue.

Mode of action

The active ingredient in Enspryng, satralizumab, blocks a substance called interleukin-6. Interleukin-6 is a substance that is released by the patient's immune system and appears to play a role in the development of neuromyelitis optica spectrum disorders. Interleukin-6 has been detected at higher levels in these patients during inflammatory episodes of the disease. Satralizumab blocks interleukin-6 activity slowing the onset of more inflammation episodes.

Use

Enspryng is available on prescription only. The first dose should be given by a qualified healthcare professional. With the agreement of the physician, subsequent injections may be administered by the patient or a caregiver. Enspryng can be prescribed for patients aged 12 and older.

The recommended dose of Enspryng is a 1 mL injection under the skin alternating between the abdomen and thigh. The injection contains 120 mg of satralizumab and should be given every 2 weeks for the first 3 injections and thereafter once every 4 weeks. This medication is intended for long-term use.

Efficacy

The efficacy of Enspryng, with the active substance satralizumab, was investigated in two trials involving 178 patients. All study participants met the criteria for the diagnosis of neuromyelitis optica.

In one study, there were 83 patients aged 12 to 74 years old. 55 participants tested positive for the aquaporin-4 IgG protein. In this study, 41 patients received satralizumab and 42 patients received a placebo. Both groups also received medication that suppressed the body's immune system response, such as oral corticosteroids, azathioprine, or mycophenolate mofetil.

The other study involved 95 adult patients, of whom 64 tested positive for the aquaporin-4 IgG protein. A total of 63 patients received satralizumab with no other medication and 32 patients received a placebo with no other medication.
Treatment with the active ingredient satralizumab, when used alone or in combination with immune system-suppressing medications, reduced the likelihood of a relapse of inflammation in the optic nerve or spinal cord compared to patients who were given a placebo.

Combined data from both studies showed that the risk of inflammation returning in patients who received satralizumab was reduced by 58 % compared with the placebo group. When looking only at patients who tested positive for the aquaporin-4 IgG protein, the risk of relapse declined by 75 %.

Analyses of longer-term data showed similar results over 120 weeks.

No benefits were observed for patients who did not test positive for aquaporin-4 IgG protein. A longer-term study involving Enspryng is ongoing with a final report expected in 2023.

Precautions, undesirable effects & risks

Enspryng may not be used if the patient has a hypersensitivity to the active ingredient satralizumab or any other substance in the injection.

Side effects were reported in most patients. They included headache (19.2%), swelling of the throat and nasal passages (18.3%), joint pain (13.5%), fatigue (8.7%), rash (8.7%), depression (6.7%), severe itching of the skin (5.8%), loss of sensation in part of the body (5.8%), a reduced number of infection-fighting white blood cells (5.8%) and injection-related reactions (12.5%), such as headache and diarrhea.

Data situation on safety and efficacy in children 12 years of age or older was limited. Only 4 patients in this age range were treated with satralizumab in one study. Safety and efficacy in children younger than 12 years old were not studied.

Known precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicine has been authorised

Neuromyelitis optica spectrum disorders are rare autoimmune inflammatory disorders of the central nervous system that damage cells in the spinal cord and the optic nerve.
These disorders can lead to severe disabilities such as blindness and paralysis within 5 years of the first symptoms. And it is estimated that nearly a third of patients whose inflammation returns (relapsing) do not live past 5 years of disease onset.

Inflammation can move into the brainstem causing nausea, hiccoughs or respiratory failure, a lung condition that reduces the amount of oxygen in the blood. Respiratory failure is the main cause of death in these patients.

Studies available so far demonstrate that patients with neuromyelitis optica spectrum disorders who tested positive for aquaporin-4 IgG protein, benefited from receiving Enspryng.

There was no benefit seen for participants who did not test positive for aquaporin-4 IgG protein.

For those who tested positive, the chance of a relapse of inflammation in the central nervous system was reduced by up to 75 percent. Adverse effects, such as headache and infection, were seen with Enspryng. However, they were also noted with the placebo group and were manageable.

Taking all the precautions into account, and based on the available data, the benefits of Enspryng outweigh the risks. Swissmedic has therefore authorised the medicine Enspryng with the active ingredient satralizumab for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Enspryng®

Healthcare professionals (doctors, pharmacists and others) may 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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