EMA/298616/2021
EMEA/H/C/004788

Enspryng (*satralizumab*)

An overview of Enspryng and why it is authorised in the EU

What is Enspryng and what is it used for?

Enspryng is a medicine used to treat patients aged 12 or above with neuromyelitis optica spectrum disorders (NMOSD), inflammatory disorders that affect mainly the optic nerve (which connects the eye to the brain), and the spinal cord. This leads to impaired vision, loss of sensation, loss of bladder control, weakness and paralysis of the arms and legs.

The medicine is used on its own or in combination with immunosuppressive therapy (treatment that reduces the activity of the immune system) in patients with antibodies against a protein called aquaporin-4 (AQP4).

NMOSD is rare, and Enspryng was designated an 'orphan medicine' (a medicine used in rare diseases) on 27 June 2016. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3161680.

Enspryng contains the active substance satralizumab.

How is Enspryng used?

Treatment with Enspryng should be started under the supervision of a doctor experienced in treating NMOSD. The medicine can only be obtained with a prescription.

Enspryng is available as a solution in a prefilled syringe to be injected under the skin of the abdomen (belly) or the thigh. Treatment starts with one injection every two weeks for the first three injections and continues with one injection every four weeks after that. Patients or their caregivers can inject Enspryng themselves after training by a healthcare professional. Vaccinations should be up to date and any infection should be well controlled before starting treatment with Enspryng. Patients should also be monitored for infection during treatment with Enspryng.

For more information about using Enspryng, see the package leaflet or contact your doctor or pharmacist.

How does Enspryng work?

In most patients with NMOSD, the disease is caused by the production of antibodies against AQP4. AQP4 is important for the normal function of nerve cells.

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The active substance in Enspryng, satralizumab, is a monoclonal antibody, a type of protein that has been designed to block the action of interleukin-6 (IL-6), a protein in the body involved in the production of antibodies against AQP4. By blocking IL-6, the medicine decreases the production of antibodies against AQP4 and therefore assures the activity of AQP4. This should prevent damage to nerve cells and reduce the symptoms of NMOSD.

What benefits of Enspryng have been shown in studies?

Enspryng was shown to be effective in increasing the length of time between relapses in patients with NMOSD in two main studies.

The first study, involving 55 patients aged 12 and above with AQP4 antibodies who were receiving immunosuppressive therapy, showed that 92% of participants taking Enspryng together with immunosuppressive therapy were relapse-free after 48 weeks, compared with 60% in participants using a placebo (dummy) treatment and immunosuppressive therapy.

A second study involving 64 adults with AQP4 antibodies showed that 83% of patients taking Enspryng were relapse-free after 48 weeks compared with 55% in those taking a placebo.

What are the risks associated with Enspryng?

The most common side effects with Enspryng (which may affect more than 1 in 10 people) are headache, arthralgia (joint pain), hyperlipidaemia (high levels of fats in the blood), decreased levels of white blood cells and injection-related reactions.

For the full list of side effects and restrictions of Enspryng, see the package leaflet.

Why is Enspryng authorised in the EU?

Enspryng is effective in preventing relapses in people with NMOSD over 12 years of age. Since the disability associated with NMOSD is severe and worsens with relapses, Enspryng was considered beneficial for these patients. NMOSD is a rare disease and the medicine was therefore tested in a small number of participants; however, the safety of the medicine was considered manageable. The European Medicines Agency therefore decided that Enspryng's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Enspryng?

The company that markets Enspryng should provide a patient alert card to inform patients about the risk of infection with Enspryng, how to recognise symptoms of infections and to seek medical attention if these arise.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Enspryng have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Enspryng are continuously monitored. Side effects reported with Enspryng are carefully evaluated and any necessary action taken to protect patients.

Other information about Enspryng

Enspryng received a marketing authorisation valid throughout the EU on 24 June 2021.

Further information on Enspryng can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/enspryng.

This overview was last updated in 06-2021.