



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/636071/2021
EMA/H/C/002127

Hizentra (*human normal immunoglobulin*)

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

What is Hizentra and what is it used for?

Hizentra is used in patients whose blood does not contain enough antibodies (proteins that help the body to fight infections and other diseases), also known as immunoglobulins. It is used to treat the following conditions:

- primary immunodeficiency syndromes (PID, when people are born with an inability to produce enough antibodies);
- secondary immunodeficiencies (SID) in people who have severe or recurrent infections that do not respond to treatments and who are unable to produce certain antibodies;
- chronic inflammatory demyelinating polyneuropathy (CIDP). In this rare disease, the immune system (the body's defense system) works abnormally and destroys the protective covering over the nerves.

Hizentra contains the active substance human normal immunoglobulin.

How is Hizentra used?

Hizentra can only be obtained with a prescription and treatment should be started by a doctor or nurse who is experienced in the treatment of patients with weakened immune systems or CIDP.

Hizentra is available as a solution for injection. It is given by subcutaneous infusion (very slow injection under the skin) through a device that controls the speed of infusion. It is given in the abdomen (belly), thigh, upper arm or hip. Patients (or their carers) may inject Hizentra at home once they have been trained.

The dose and how often Hizentra infusion is given depend on the disease being treated. The dose may need to be adjusted depending on how well the medicine is working.

For more information about using Hizentra, see the package leaflet or contact a doctor or pharmacist.

How does Hizentra work?

The active substance in Hizentra, human normal immunoglobulin, is a highly purified protein extracted from donated human blood. It contains mainly immunoglobulin G (IgG), which is composed of a range

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of antibodies involved in fighting organisms that can cause infection. Hizentra works by restoring abnormally low IgG levels to their normal range in the patient's blood. It can also help to control the immune system when it is working abnormally such as in CIDP. Normal immunoglobulin has been used as a medicine since the 1980s.

What benefits of Hizentra have been shown in studies?

As human normal immunoglobulin has been used to treat these diseases for many years, in accordance with current guidelines, two small studies and an analysis of scientific literature were needed to establish the effectiveness and safety of Hizentra in patients.

In the first study, Hizentra was investigated in 51 patients with PID who had already received human immunoglobulin into a vein for at least six months. The patients received Hizentra for 28 weeks and the lowest IgG levels during treatment with Hizentra (average level of 8.1 g per litre) were comparable to those seen during previous immunoglobulin treatment. IN addition, no infections occurred during the study period.

In the second study Hizentra was studied in 172 patients with CIDP who had previously received human immunoglobulin treatment by injection into a vein. Patients received Hizentra or placebo (a dummy treatment) for 13 weeks and the study measured the proportion of patients in whom the disease came back within 13 weeks. For patients on placebo, the disease came back in about 63% of patients, for patients on Hizentra, the disease came back in 33 and 39% of patients; depending on the dose used.

The scientific literature analysis involved seven studies comparing the use of Hizentra in patients with SID with other subcutaneous infusion or intravenous (injected directly into a vein) immunoglobulin treatments. All studies showed increases in antibody levels and/or a reduction in infection rates after receiving Hizentra or another subcutaneous immunoglobulin treatment; the effects were comparable to those seen with intravenous immunoglobulin treatment.

What are the risks associated with Hizentra?

The most common side effects with Hizentra (which may affect more than 1 in 10 people) are headache, rash, muscle and joint pain (including muscle spasm and weakness), reactions around the injection area (swelling, soreness, redness, pitting, warmth, itching, bruising and rash) and flu-like illness. Rarely patients may have a sudden drop in blood pressure or an anaphylactic shock (sudden, severe allergic reaction).

Hizentra must not be used in patients with hyperprolinaemia (a genetic disorder causing high levels of the amino acid proline in the blood). It must not be injected into a blood vessel.

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

Why is Hizentra authorised in the EU?

The European Medicines Agency decided that Hizentra's benefits are greater than its risks and it can be authorised for use in the EU. Hizentra was shown to prevent serious bacterial infections in patients with PID or SID and reduce the chance of CIDP coming back. It may be given at home, with manageable side effects.

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

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

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

Other information about Hizentra

Hizentra received a marketing authorisation valid throughout the EU on 14 April 2011.

Further information on Hizentra can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/hizentra.

This overview was last updated in 11-2021.