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HyQvia (*human normal immunoglobulin*)

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

What is HyQvia and what is it used for?

HyQvia is used in adults and children with immunodeficiency syndromes. These are patients whose blood does not contain enough antibodies (proteins that help the body to fight infections and other diseases), also known as immunoglobulins.

HyQvia is used to treat:

- primary immunodeficiency syndromes (PID, when patients are born with an inability to produce enough antibodies);
- secondary immunodeficiency syndrome (SID, when patients have developed inability to produce enough antibodies as a result of another condition or treatment). HyQvia is used in patients who have serious or recurrent infections for which current treatments do not work and who have low blood levels of immunoglobulin G (IgG) or who are not able to produce sufficient levels of IgG in response to infections;
- chronic inflammatory demyelinating polyneuropathy (CIDP) after the patient is stabilised on intravenous immunoglobulins. In this condition, the immune system (the body's defence system) works abnormally and destroys the protective covering over the nerves causing nerve problems such as weakness and numbness.

HyQvia contains the active substance human normal immunoglobulin. The product also contains recombinant human hyaluronidase, which is an enzyme used to help the active substance to disperse under the skin and improve its absorption into the body.

How is HyQvia used?

HyQvia can only be obtained with a prescription and treatment should be started and monitored under the supervision of a doctor experienced in treating immunodeficiency syndromes or CIDP.

HyQvia is available as two solutions for infusion (drip) under the skin. A solution containing recombinant human hyaluronidase is given first and a solution containing human normal immunoglobulin is then given by infusion in the same place. For more information about using HyQvia, see the package leaflet or contact your doctor or pharmacist.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The dose and frequency of infusions (how often it is given) depend on the patient's weight and the disease it is used for and may need to be adjusted depending on the response to treatment. Patients or their carers may be able to give HyQvia themselves once they have been trained appropriately.

How does HyQvia work?

The active substance in HyQvia, human normal immunoglobulin, is a highly purified protein extracted from the blood. It contains IgG, which is a class of antibodies with a wide range of activity against organisms that can cause infection. HyQvia works by restoring abnormally low IgG levels to their normal range in the blood. It can also help to maintain the balance in the immune system when it is working abnormally, such as in CIDP.

HyQvia also contains recombinant human hyaluronidase. This is a form of the natural human enzyme, hyaluronidase, which breaks down a substance called hyaluronic acid that is present in the tissues in the tiny spaces between cells and temporarily increases the amount of fluid in the area between cells. When given under the skin before the human normal immunoglobulin, it helps the active substance to disperse under the skin and allows more of it to be absorbed.

What benefits of HyQvia have been shown in studies?

Human normal immunoglobulin has been used to treat these diseases for many years. HyQvia was evaluated in one main study lasting over a year and involving 89 adults and children with PID who had already been treated with human normal immunoglobulin for at least three months.

The study showed that HyQvia was able to reduce the number of serious bacterial infections to 0.03 per patient per year. This was below the predefined number needed to show effectiveness (which is considered to be one infection per year), and was similar to that seen with other authorised human normal immunoglobulin products.

This study was extended to almost 4 years and confirmed the long-term benefits and safety of HyQvia.

HyQvia was found to be effective in treating SID based on the results in patients with PID and the similarities between PID and SID.

An additional study involving 138 adults with CIPD who had previously received human immunoglobulin treatment by injection into a vein measured the proportion of patients in whom the disease came back within 6 months. The study found that 16% of patients on HyQvia had a relapse compared with 32% on placebo. Although HyQvia was not studied in children with CIPD, based on the characteristics of the medicine, it is expected to have similar effects in children. In addition there is extensive clinical experience with the use of this medicine in children supporting the use in children with CIPD.

What are the risks associated with HyQvia?

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

The most common side effects with HyQvia (which may affect more than 1 in 10 people) include local reactions such as swelling and discomfort at the site of the infusion.

HyQvia must not be used in people who are hypersensitive (allergic) to human normal immunoglobulin or hyaluronidase or any of the other ingredients, or in patients who are allergic to other types of

immunoglobulins, especially where they have deficiency (very low levels) of immunoglobulin A (IgA) and they have antibodies against IgA. HyQvia must not be given into a blood vessel or a muscle.

Why is HyQvia authorised in the EU?

The European Medicines Agency concluded that for PID and SID HyQvia produces a similar reduction in the number of serious bacterial infections to that seen with other immunoglobulin products. In CIPD, maintenance treatment with HyQvia reduces relapses. Using recombinant hyaluronidase allows infusions under the skin to be given at much longer intervals, although local reactions are slightly more common. The possibility of patients or their carers giving the medicine themselves at home may also improve the convenience of giving the product. Although there had been concerns that antibodies that develop against recombinant hyaluronidase could affect the natural enzyme in the body and cause side effects, this has not been confirmed in studies. The Agency therefore decided that HyQvia'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 HyQvia?

The company that markets HyQvia must provide educational material for healthcare professionals and patient cards with information about how to prepare and give the medicine as well as the risks of allergic and infusion-related reactions.

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

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

Other information about HyQvia

HyQvia received a marketing authorisation valid throughout the EU on 16 May 2013.

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

This overview was last updated in 12-2023.