EMA/370423/2016
EMEA/H/C/002491

EPAR summary for the public

HyQvia

Human normal immunoglobulin

This is a summary of the European public assessment report (EPAR) for HyQvia. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use HyQvia.

For practical information about using HyQvia, patients should read the package leaflet or contact their doctor or pharmacist.

What is HyQvia and what is it used for?

HyQvia is used in patients 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 as 'replacement therapy' to treat:

- primary immunodeficiency syndromes (PID, when patients are born with an inability to produce enough antibodies);
- low levels of antibodies in the blood in patients who have chronic lymphocytic leukaemia or myeloma (two cancers affecting different types of white blood cell) and who have frequent infections.

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

HyQvia contains the active substance human normal immunoglobulin.

How is HyQvia used?

HyQvia can only be obtained with a prescription and treatment should be started and monitored by a doctor or nurse experienced in treating immunodeficiency syndromes.

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 (100 mg/ml) is then given by infusion in the same place. Detailed information about using HyQvia is provided in the package leaflet.

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

How does HyQvia work?

The active substance in HyQvia, human normal immunoglobulin, is a highly purified protein extracted from the blood. It contains immunoglobulin G (IgG), which is a type of antibody. IgG has been used as a medicine since the 1950s and has 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.

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 so makes the area between cells temporarily more liquid. When given under the skin before the normal human immunoglobulin, it helps to deliver the active substance under the skin, and assists its absorption into the body.

What benefits of HyQvia have been shown in studies?

Human normal immunoglobulin has been used to treat these diseases for many years. In accordance with current guidelines for these medicines, HyQvia was investigated in one main study lasting over a year and involving 89 patients with PID who had already had treatment with human normal immunoglobulin for at least three months. The main measure of effectiveness was the number of serious bacterial infections that developed over one year of treatment.

The study showed that HyQvia was able to reduce this number to 0.03 per year. This was below the predefined number needed to show effectiveness (which is one infection per year), and was similar to that seen with other licensed human normal immunoglobulin products.

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

What are the risks associated with HyQvia?

The most common side effects with HyQvia (which may affect more than 1 in 10 people) are local reactions such as swelling and discomfort at the site of the infusion. For the full list of all side effects reported with HyQvia, see the package leaflet.

HyQvia must not be used in people who are hypersensitive (allergic) to normal human 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 approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that HyQvia produces a similar reduction in the number of serious bacterial infections to that seen with other immunoglobulin products, and using recombinant hyaluronidase allows subcutaneous infusions 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 the product. Although there had been concerns that antibodies that develop against recombinant hyaluronidase could cause side effects by affecting the natural version of the enzyme, the results of studies were

reassuring. The Committee therefore decided that HyQvia's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

Other information about HyQvia

The European Commission granted a marketing authorisation valid throughout the European Union for HyQvia on 16 May 2013.

The full EPAR for HyQvia can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with HyQvia, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2016.