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Deqsiga (*human normal immunoglobulin*)

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

What is Deqsiga and what is it used for?

Deqsiga is a medicine used to treat people who:

- are at risk of infection because they lack a type of antibody called immunoglobulin G (IgG), which is a protein in the blood that helps the body fight infections. Deqsiga is used in people who are born with a lack of IgG (primary immunodeficiency syndrome, PID) and those who developed a lack of IgG after birth (secondary immunodeficiency syndrome, SID) and have infections that are severe or keep coming back, and for which medicines used to treat infections do not work;
- have certain immune diseases (caused by the body's own defence system attacking normal tissues), to help the activity of the immune system (immunomodulation). Deqsiga is used in patients with:
  - primary immune thrombocytopenia (ITP), a disease associated with a lack of platelets (components in the blood that help it to clot) which puts patients at risk of bleeding;
  - Guillain-Barré syndrome and chronic inflammatory demyelinating polyradiculoneuropathy, inflammatory disorders of the nerves that result in muscle weakness and numbness;
  - Kawasaki disease, a disease mainly seen in children which causes inflammation of blood vessels;
  - multifocal motor neuropathy, nerve damage which causes weakness of the arms and legs.

Deqsiga contains the active substance human normal immunoglobulin.

How is Deqsiga used?

The medicine can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in treating patients with immune system disorders.

Deqsiga is given by infusion (drip) into a vein. Patients with immunodeficiency receive Deqsiga every 3 to 4 weeks. How often the medicine is given for immunomodulation depends on the condition being treated.

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

How does Deqsiga work?

Deqsiga contains the active substance human normal immunoglobulin, consisting of antibodies that have been extracted and purified from the plasma (the liquid part of blood) of healthy people. In patients with primary or secondary immunodeficiency, Deqsiga provides the IgG they lack, lowering their risk of infection. At higher doses, Deqsiga helps reduce the activity of the immune system in people with autoimmune disorders.

What benefits of Deqsiga have been shown in studies?

As human normal immunoglobulin has been used to treat immunodeficiency syndrome and immune disorders for a long time, 4 small studies were sufficient to establish the effectiveness of Deqsiga in patients with immunodeficiency or immune disorders.

PID

Two main studies showed that Deqsiga is effective in preventing infections in patients with PID. The main measure of effectiveness was the frequency of infection in patients. To identify signs of infection, patients had blood drawn before each infusion of Deqsiga, and 3 weeks after the last infusion.

The first study involved 22 patients who received 3 infusions of an authorised immunoglobulin medicine, followed by 9 infusions of Deqsiga, given 3 weeks apart. During treatment with Deqsiga, non-serious infections occurred at an average of 0.48 times per patient per month, with no serious infection occurring. Additionally, courses of antibiotics were required at an average of 0.18 times per patient per month.

The second study involved 61 patients who received Deqsiga for 12 months, every 3 to 4 weeks. During treatment, non-serious infections occurred at an average of 0.07 times per patient per year, with no serious infection occurring.

Immunomodulation

Two main studies showed that Deqsiga is effective in reducing the activity of the immune system in patients with immune disorders.

The first study involved 28 patients with ITP who received a short 2-to-5-day treatment with Deqsiga. Within 15 days of starting treatment, 74% of patients reached normal platelet levels, reducing their risk of bleeding.

The second study involved 44 patients with multifocal motor neuropathy. All patients first received Deqsiga for 36 weeks. They were then treated with Deqsiga for 12 weeks before switching to placebo (a dummy treatment) for 12 weeks, or vice versa. At the end of each treatment period, muscle strength was evaluated by recording the patients' grip strength and using a questionnaire that scored their level of disability. The average difference in grip strength between the two treatment periods was 34%, meaning that patients had improved grip strength when treated with Deqsiga compared with placebo. Additionally, 36% of patients had greater disability during treatment with placebo, while they remained stable on Deqsiga; 12% worsened on Deqsiga and remained stable on placebo. Furthermore, 69% of patients had to switch to Deqsiga while receiving placebo because their symptoms had worsened significantly.

What are the risks associated with Deqsiga?

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

The most common side effects with Deqsiga (which may affect more than 1 in 10 people) include headache, hypertension (high blood pressure), nausea (feeling sick), rash, tiredness, local reactions such as pain, swelling and itching at the site of injection, and fever. Some side effects are more likely when the infusion is given in a short time, in patients with low immunoglobulin levels, who have not received Deqsiga for a long time or who have never received it.

Deqsiga must not be used in people with selective IgA deficiency who developed antibodies to IgA, as this may lead to anaphylaxis (a severe allergic reaction).

Why is Deqsiga authorised in the EU?

Deqsiga was shown to be effective in reducing the risk of infection in patients with PID and improving symptoms of ITP and multifocal motor neuropathy. Based on these results, Deqsiga is expected to alleviate symptoms of Guillain-Barré syndrome, Kawasaki disease and chronic inflammatory demyelinating polyradiculoneuropathy. Therefore, specific studies in these diseases are not necessary.

Deqsiga contains low levels of IgA, which may lower the risk of allergic reactions, especially in patients who lack IgA and have a higher risk of allergic reactions to immunoglobulin medicines containing higher levels of IgA.

Medicines containing human normal immunoglobulin have been used in the EU since the 1980s. Deqsiga's side effects are similar to those of other medicines in the same class; they are mostly mild to moderate and temporary. Severe side effects may occur rarely with Deqsiga, including severe allergic reactions (which may occur in up to 1 in 100 people).

The European Medicines Agency therefore decided that Deqsiga'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 Deqsiga?

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

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

Other information about Deqsiga

Deqsiga received a marketing authorisation valid throughout the EU on 2 May 2025.

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

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