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EPAR summary for the public

ImmunoGam

human hepatitis B immunoglobulin

This document is a summary of the European Public Assessment Report (EPAR) for ImmunoGam. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for ImmunoGam.

What is ImmunoGam?

ImmunoGam is a solution for injection that contains the active substance human hepatitis B immunoglobulin.

What is ImmunoGam used for?

ImmunoGam is used to provide protection against the hepatitis B virus. ImmunoGam provides 'passive' protection. This means that it supplies the antibodies the body needs to fight the virus rather than stimulating the body to produce its own. ImmunoGam can be used in the following people, who need immediate protection:

- people accidentally exposed to the virus who are not known to have been vaccinated fully;
- patients who have had haemodialysis (a blood clearance technique used in people with kidney problems). In these patients it is used until vaccination against the virus becomes effective;
- newborn babies whose mothers are carriers of the virus;
- people at continuous risk of hepatitis B infection who have not responded to vaccination.

The medicine can only be obtained with a prescription.

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How is ImmunoGam used?

ImmunoGam is given as an injection into a muscle. It is highly recommended that all those receiving ImmunoGam should also be given a hepatitis B vaccine.

People accidentally exposed to the virus should receive at least 500 international units (IU) as soon as possible and preferably within 24 to 72 hours of exposure. Haemodialysed patients should received 8 to 12 IU per kilogram body weight up to a maximum of 500 IU, every two months. Newborn babies whose mothers are carriers of the hepatitis B virus should receive 30 to 100 IU/kg at birth or as soon as possible after birth. This may need to be repeated until the babies show an immune response against the virus after vaccination. Finally, people at continuous risk of hepatitis B infection who did not show an immune response after vaccination may be given 500 IU (in adults) or 6 IU/kg (in children) every two months.

Doctors should also consider other official guidance when choosing a dose and dosing schedule for ImmunoGam

How does ImmunoGam work?

The active substance in ImmunoGam, human hepatitis B immunoglobulin, is a purified antibody extracted from human blood. Antibodies are proteins in the blood that help the body to fight infections and other diseases. ImmunoGam protects against the hepatitis B virus by keeping the blood levels of human hepatitis B immunoglobulins high enough so that they can attach to the virus and stimulate the immune system to destroy it.

Medicines containing human hepatitis B immunoglobulins have been used in the European Union (EU) for many years.

How has ImmunoGam been studied?

Although ImmunoGam itself was not tested in experimental models, the applicant presented adequate data from studies using similar medicines.

ImmunoGam has been investigated in one main study involving 253 newborn babies whose mothers were carriers of the virus and 42 adults who had potentially been exposed to the virus. All those who received ImmunoGam were also given a hepatitis B vaccine. The main measure of effectiveness was the number of people who remained free of hepatitis B infection. The patients were followed up for up to a year. Because only a small number of adults were involved in the study, the assessment of the medicine's benefits was based mainly on the results from the babies.

What benefit has ImmunoGam shown during the studies?

ImmunoGam was effective at protecting against hepatitis B virus infection. Of the 178 babies who completed the study, 174 (98%) remained free of hepatitis B infection. This is comparable to the protection rate seen with similar treatments in published literature. The results in adults also provided some supportive evidence to show that ImmunoGam protects against hepatitis B virus infection.

What is the risk associated with ImmunoGam?

Side effects with ImmunoGam are not common. However, the following side effects are seen in between 1 and 10 patients in 1,000: headache, dizziness, nausea, arthralgia (joint pain), back pain, myalgia (muscle pain), fatigue (tiredness), induration (hardening at the injection site), malaise (feeling unwell), pain at injection site and pyrexia (fever).

ImmunoGam should not be used in people who may be hypersensitive (allergic) to the active substance, to any of the other ingredients or to human immunoglobulins, especially where they have deficiency (very low levels) of immunoglobulin A (IgA) and they have antibodies against IgA.

Why has ImmunoGam been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that ImmunoGam's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about ImmunoGam:

The European Commission granted a marketing authorisation valid throughout the EU for ImmunoGam to Cangene Europe Limited on 16 March 2010. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for ImmunoGam can be found here. For more information about treatment with ImmunoGam, read the Package Leaflet (also part of the EPAR).

This summary was last updated in 04-2010.