▼ This medicinal product is subject to additional monitoring.

Abbreviated prescribing information for cutaquig® (165 mg/ml, Human Normal immunoglobulin)

This information is designed for international use and may deviate from the product information valid in your country. Please refer to your national Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Solution for injection containing 165 mg /ml human normal immunoglobulin of which ≥95% is IgG. IgA content ≤ 0.6 mg/ml.
Indications: Replacement therapy in adults, children and adolescents (0-18 years) in Primary immunodeficiency syndromes (PID) with impaired antibody production; Secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF)* or serum IgG level of <4g/l. (*PSAF = failure to mount at least a 2-fold rise in IgG antibody titre to pneumococcal polysaccharide and polypeptide antigen vaccines)
Dosage and Method of Administration: Subcutaneous infusion for home treatment should be initiated and monitored by a health care professional experienced in the guidance of patients for home treatment. The patient and/or a caregiver must be properly instructed. For subcutaneous use. Dosage needs to be individualised dependent on the pharmacokinetics and clinical response to achieve a sustained IgG level of at least 5 to 6 g/l and aim to be within the reference interval of serum IgG for age. Cutaquig can be administered at regular intervals from daily up to every other week.
Replacement therapy in primary immunodeficiency syndromes: Loading dose of at least 0.2 - 0.5 g/kg may be required to achieve steady state. This may need to be divided over several days, with a maximal daily dose of 0.1 to 0.15 g/kg. Maintenance doses at repeated intervals to reach a cumulative monthly dose of 0.4-0.8 g/kg. It might be necessary to administer the daily dose on more than one injection site.
Replacement therapy in secondary immunodeficiencies: The recommended dose administered at repeated intervals is to reach a cumulative monthly dose of the order of 0.2-0.4 g/kg (1.2 – 2.4 ml/kg). Each single dose may need to be injected at different anatomic sites.
Infusion rate and infusion volume per site are based on subject tolerability. Initial administration rate: 15 ml/h/site. From infusion 7 on, if well tolerated, gradually increase to 25 mL/h/site. Infusion rate per h for all sites combined: 30 mL/h for first 6 infusions, then, if tolerated, gradually increase to max 80 mL/h for all sites. The amount of product infused into a particular site varies. In infants and children, infusion site may be changed every 5-15 ml. In adults, doses over 30 ml may be divided according to patient preference. There is no limit to the number of infusion sites. Infusion sites should be at least 5 cm apart.
Contraindications: Hypersensitivity to the active substance or any of the excipients. Do not infuse intravenously. No intramuscular administration in case of severe thrombocytopenia or other disorders of haemostasis.
Special Warnings and Precautions: cutaquig contains 90 mg of maltose per ml. Interference of maltose with certain blood glucose assays may result in falsely elevated glucose readings and in inappropriate administration of insulin resulting in life threatening hypoglycaemia and death, also true cases of hypoglycaemia may go untreated. Always read product information of your blood glucose testing system. Record the name and the batch number for each infusion. Risk of shock if accidentally administered into a blood vessel. Adverse reactions may occur more frequently if administered at a high rate of infusion, in patients new to human normal immunoglobulin, in patients switching product or when there has been a long interval since the previous infusion. In case of adverse reaction, either decrease rate of administration or stop the infusion. Additional treatment depends on the nature and severity of the adverse reaction. Hypersensitivity reactions are rare. Anaphylaxis can develop in patients with undetectable IgA who have anti-IgA antibodies or in patients who had tolerated previous treatment with human normal immunoglobulin. In case of shock, standard medical treatment for shock should be implemented. There is clinical evidence of an association between immunoglobulin administration and thromboembolic events such as myocardial infarction, cerebral vascular accident (including stroke), pulmonary embolism and deep vein thromboses. Risk factors associated with thromboembolic events are obesity and e.g. advanced age, hypertension, diabetes mellitus, a history of vascular disease or thrombotic episodes, acquired or inherited thrombophilic disorders or prolonged periods of immobilisation, severe hypovolaemia, diseases that increase blood viscosity. There is clinical evidence of association between immunoglobulin administration and acute renal failure. Risk factors associated with renal complications are e.g. pre-existing renal insufficiency, diabetes mellitus, hypovolemia, overweight, concomitant nephrotoxic medicinal products, sepsis, hyperviscosity, paraproteinaemia or age over 65. Aseptic meningitis syndrome (AMS) has been reported in connection with immunoglobulin treatment. The transitory rise of passively transferred antibodies during/after immunoglobulin injection may result in misleading positive results in serological testing. When medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. IgG products can contain blood group antibodies that may act as hemolysins and induce in vivo coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin (Coombs') test result and, rarely, may cause haemolysis. This medicinal product contains 33.1 mg sodium per vial of 48 mL and 13.8 mg sodium per vial of 20 mL.
Interactions: Immunoglobulin administration may impair for a period of at least 6 weeks and up to 3 months (up to 1 year in case of measles) the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella.
Undesirable effects: Injection site reactions may frequently occur. Chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain may occur occasionally. Rarely human normal immunoglobulins may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock. For a full list of undesirable effects, see section 4.8 of your local SmPC.
Special precautions for disposal and storage*:* The shelf life is 3 years at +2 to +8°C. Within its shelf-life, the product may be stored at room temperature (≤ 25°C) for up to 6 months without being refrigerated again and must be discarded if not used after this.
Do not freeze. Protect from light. The product should be brought to room or body temperature before use.
Legal Category: POM.
Marketing Authorisation Number: refer to your local Country for relevant information
Marketing Authorisation Holder: Octapharma AG, Seidenstrasse 2, CH-8853 Lachen, Switzerland
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Adverse events should be reported to safetyreporting@octapharma.com.