

Pentaglobin – Basic Information

Pentaglobin 50 mg/ml solution for infusion. **Active substance:** Human immunoglobulin. **Composition:** 1 ml solution contains 50 mg human plasma protein, min. 95 % immunoglobulin with IgM 6 mg, IgA 6 mg and IgG 38 mg (IgG subcl. approx. 63 % IgG1, 26 % IgG2, 4 % IgG3 and 7 % IgG4), Glucose monohydrate, sodium chloride, water for injections. **Therapeutic indications:** Treatm. of (severe*) bacterial infections with concomit. antibiotic therapy. Immunoglobulin replacem. therapy f. immunosuppr. patients and those with severe sec. antibody deficiency syndr. (immunocomprom. patients and those with a suppressed immune system). **Contraindications:** Hypersensitivity to the active substance or any of the excipients; pat. with select. IgA deficiency with antibodies to IgA. **Warnings:** One daily dose of approx. 350 ml contains 8.75 g glucose (correspond. to approx. 0.735 bread units), to be considered for patients with diabetes mellitus, and 627.6 mg sodium, (correspond. to approx. 31% of recomm. daily intake for an adult). **Undesirable effects:** Headache, joint-/ back pain, chills, dizziness, fever, nausea, vomiting, hyperhidrosis, dyspnoea, flushing, tachy- or bradycardia, hypersensitivity, allerg. /anaphylactoid react., anaphylact. shock, sudden fall in blood pressure, low blood pressure, revers. haemolyt. react., haemolytic anaemia, haemolysis, thromboembol. react. (e.g. myocardial infarction, stroke, pulmonary embolism, deep vein thrombosis), (revers.) aseptic meningitis, (trans.) skin react. (e.g. skin reddening, itching, allerg. dermatitis, cut. lupus erythematosus) increase in serum creatinine level, acute renal failure, TRALI, tachypnea, oxygen satur. decreased, skin discolorations includ. pallor and/or cyanosis, hypotonia.

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*depending on local approved indication