Prescribing Information

Intratect® 50 g/l and 100 g/l Human normal immunoglobulin solution for intravenous infusion
Please consult full Summary of Product Characteristics (SmPC) before prescribing

Intratect is a solution containing either 50 g/l or 100 g/l human normal immunoglobulin (IVIg), purity at least 96% IgG. Intratect 50 g/l 20 ml vial contains 1 g, 50 ml vial 2.5 g; 100 ml vial 5 g and 200 ml vial 10 g of IVIg. Intratect 100 g/l 10ml vial contains 1 g, 25 ml vial 2.5 g, 50 ml vial 5 g, 100 ml vial 10 g and 200 ml vial 20 g of IVIg.

Indications and dosing: ***Replacement therapy in***: *Primary immunodeficiency syndromes (PID)* with impaired antibody production, starting dose 0.4-0.8 g/kg once, thereafter 0.2-0.8 g/kg every 3-4 weeks; the dose regimen should achieve a trough level of IgG of at least 6 g/l or within the normal reference range for the population age. *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 <4 g/l. (*PSAF= failure to mount at least a 2-fold rise in IgG antibody titre to pneumococcal polysaccharide and polypeptide antigen vaccines). The recommended dose is 0.2-0.4 g/kg every three to four weeks.

In both PID and SID IgG trough levels should be measured and assessed in conjunction with the incidence of bacterial infection.

Immunomodulation in: *Primary immune thrombocytopenia (ITP)*, in patients at high risk of bleeding or prior to surgery to correct the platelet count, there are two alternative treatment schedules: 0.8-1 g/kg given on day one, this dose may be repeated once within 3 days or, 0.4 g/kg given daily for two to five days. The treatment can be repeated if relapse occurs. *Guillain Barré syndrome*: 0.4 g/kg/day over 5 days (possible repeat of dosing in case of relapse). *Kawasaki disease*: 2.0 g/kg as a single dose, concomitantly with acetylsalicylic acid. *Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) Starting dose* 2 g/kg in divided doses over 2-5 consecutive days, maintenance doses 1 g/kg over 1-2 consecutive days every 3 weeks. *Multifocal motor neuropathy (MMN):* Starting dose 2 g/kg over 2-5 consecutive days, maintenance dose 1 g/kg every 2-4 weeks or 2 g/kg every 4-8 weeks. For both CIDP and MNN, treatment should be evaluated after each cycle and discontinued after 6 months if no treatment effect seen. If the treatment is effective, long term treatment should be subject to physicians discretion.

The dose and infusion rate may need to be individualised for each patient dependent on the clinical response, but initially infusion rate not more than 1.4 ml/kg/h for 30 minutes which can be increased gradually up to 1.9 ml/kg/h if well tolerated. In replacement therapy with Intratect 100 g/l, if patients have tolerated the infusion rate of 1.9 ml/kg/h well, the rate may be gradually increased to 6 ml/kg/h and if still well tolerated, then further increased gradually to a maximum of 8 ml/kg/h.

Contraindications and precautions: Hypersensitivity to the active substance (human immunoglobulins) or to any of the excipients. Patients with selective IgA deficiency who developed antibodies to IgA, as administering an IgA-containing product can result in anaphylaxis. Record name and batch number to aid traceability. Potential complications can often be avoided by initially injecting slowly, to ensure patient is not sensitive and carefully monitoring in hospital for symptoms during and for at least 20 minutes after infusion (1 hour for those at risk of more frequent adverse reactions as noted). In all patients adequate hydration, monitoring of urine output and creatinine levels and avoidance of loop diuretics is required. Certain adverse reactions occur more frequently with high infusion rates, when a patient is IVIg naïve, or, in rare cases when human normal immunoglobulin product is switched or after long interval since previous infusion, or in patients with an untreated infection or underlying chronic inflammation. Caution in patients who are obese or with pre-existing risk factors for thrombotic events and risk factors for acute renal failure. Clinicians should observe patients for aseptic meningitis syndrome (AMS), haemolytic anaemia, leukopenia and pulmonary adverse events. **Refer to SmPC for all special warnings and precautions.**

Undesirable effects: *In decreasing frequency;* chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain. Reversible haemolytic reactions and (rarely) haemolytic anaemia requiring transfusion. *Rarely;* A sudden fall in blood pressure and, in isolated cases, anaphylactic shock. Transient cutaneous reactions. *Very rarely;* Thromboembolic reactions such as myocardial infarction, stroke, pulmonary embolism, deep vein thromboses, reversible aseptic meningitis, increased serum creatinine level and/or acute renal failure, transfusion related acute lung injury (TRALI). *Frequency unknown;* angina pectoris, rigors, dyspnoea, shock and leukopenia. **Please refer to SmPC for further details of adverse events Shelf life:** 3 years. Do not store above 25°C. Do not freeze. **Legal category:** POM. **MA number:** Intratect® 50 g/l PL 04500/0005; 100 g/l PL 04500/0013 **MA holder:** Biotest Pharma GmbH. Landsteinerstrasse 5, 63303 Dreieich, Germany. **Revision of prescribing information:** January 2019.

Further information can be obtained from Aquilant Specialist Healthcare Services, 21 Fonthill Business Park, Fonthill Rd, Clondalkin Dublin 22, D22 FR82. Telephone: +353 1 404 8330

Adverse events should be reported to quality@aquilantservices.com. Adverse events can also be reported to Biotest (UK) Ltd. on medicinesinformation.uk@biotest.com.