Immunoglobulin (Intratect) 10% Intravenous for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- Use Online Dosage Calculator and Order Form
- **Please ensure you are using the correct monograph- separate monographs for both 5% and 10% strengths are available**
- See over for **monitoring** requirements
- This is a **blood product**, therefore batch and expiry information should be recorded in the patient's notes. This is facilitated by putting the dispensing label from each vial into the patient's notes.
- Licensed doses vary with the brand of immunoglobulin employed. Discuss with your consultant or pharmacy if further information required.
- **Contraindicated** in individuals with known **class specific antibody to Immunoglobulin A**
- **Thromboembolism:** Use caution with IVIg in **obese patients** and in patients with **pre-existing risk factors for thrombotic events**. In patients at risk for thromboembolic adverse reactions, IVIg products should be administered at the **minimum rate of infusion and dose practicable**
- **Glass bottle precautions** as follows:
- Precautions need to be taken during administration to prevent possible air embolism - particularly in central line administration. Bottles must be vented in one of two ways:
  - Directly by means of a filter needle into the bottle which goes through the rubber stopper and opens into the air
  - or Direct air vent on the air inlet of the administration set, located between the drip chamber and piercing pin, it is covered with a bacterial retentive filter to reduce the chance of contamination

Available preparations

Intratect 5g human normal immunoglobulin per 50ml vial

Intratect 10g human normal immunoglobulin per 100ml vial

Intratect 20g human normal immunoglobulin per 200ml vial

Reconstitution

Already in solution

Infusion fluids

Not required (product ready for infusion)

Methods of intravenous administration

Intermittent intravenous infusion (using an electronically controlled infusion device)

- First 30 minutes: maximum rate of 0.3ml/kg/hour

- If well tolerated, the rate may then be gradually increased to a maximum of 1.9ml/kg/hour for the remainder of the infusion - see rate table at bottom of monograph
- For **Replacement therapy patients only**, (patients with immunodeficiency, who have tolerated the infusion rate of 1.9ml/kg/hour well, the rate may be gradually increased to 6ml/kg/hour and if still tolerated well, it may be further increased gradually to a maximum of 8ml/kg/hour
- If reaction occurs during infusion, see 'Further information' for guidance
- When prescribed as a daily dose over several days, the rate will need to be titrated again on each day. However, if it was well tolerated the previous day, the rate may be increased more quickly on subsequent days. (ref 1)
- If prescribed as a daily dose, and on day one it is first administered late in the day, on subsequent days the starting time for administration may be brought back to earlier in the day if required. Gradual titration of the rate will be needed on each day, as before.

Infusion rates for INTRATECT 10%- sample calculations. See above for exceptions to rate increases

If a patient's weight falls between two values below, use the lower infusion rate- e.g. patient weight 59kg- use rates for 55kg rather than for 60kg

Increase rate as per table below, every 30 minutes as tolerated - until the full dose has been administered
Maintain low rate of infusion throughout if patient has acute renal disease, or thromboembolic disorders

Weight (kg)	First 30 minutes (ml/hour)	Second 30 minutes (ml/hour)	Third 30 minutes (ml/hour)	Usual maximum rate (ml/hour)
Â	0.3ml/kg/hour	0.6ml/kg/hour	1.2ml/kg/hour	1.9ml/kg/hour
50	15	30	60	95
55	16.5	33	66	105
60	18	36	72	114
65	19.5	39	78	124
70	21	42	84	133
75	22.5	45	90	143
80	24	48	96	152
85	25.5	51	102	162
90	27	54	108	171
95	28.5	57	114	181
100 (max weight to use for RATE calculations*)	30	60	120	190

Rates above are for most patients. Replacement therapy: patients may tolerate gradual increases up to 6ml/kg/hour or even up to 8ml/kg/hour (three to four times maximum rates given above)
*** max 100kg used to calculate dose RATE** - based on requirement not to overload heavy patients with high rate of large volume infusions

Dose in adults

Important points (ref 2)

- Use Online Dosage Calculator and Order Form
- Using this adjusted weight dose may contribute to minimisation of side-effects and will also save significant quantities of immunoglobulin.

Replacement therapy in primary immunodeficiency

- 0.4g/kg to 0.8g/kg initially, followed by 0.2g/kg to 0.8g/kg every three to four weeks thereafter, depending on the clinical response and on the IgG trough level.
- Desired trough levels (taken before the next infusion) are at least 6g/L
- Three to six months are required after initiation of therapy for equilibration to occur

Replacement therapy in secondary immunodeficiency

- 0.2g to 0.4g/kg every three to four weeks thereafter, depending on the clinical response
- IgG trough levels should be measured and assessed in conjunction with the incidence of infection. Dose should be adjusted as necessary to achieve optimal protection against infections, an increase may be necessary in patients with persisting infection; a dose decrease can be considered when the patient remains infection free.

Idiopathic thrombocytopenia (ITP)

- 0.4g/kg daily for two to five days
- Alternative regimen: 0.8g/kg to 1g/kg on day 1, which may be repeated within three days if relapse occurs

Guillain Barre Syndrome

- Give 0.4g/kg daily for five days

See SPC for other indications

It is common practice for **neurology patients** to be prescribed enoxaparin 40mg od subcutaneously due to the increased risk of thromboembolism. Consider prescribing but check dose etc with Registrar first. See also under Important information re thromboembolism

Monitoring

- Patients must be **closely monitored** and carefully observed for any adverse reactions throughout the infusion period and for at least twenty minutes after administration
- Monitoring should be **extended to one hour** for immunoglobulin naive patients, those switched from another product, or when there has been a long interval since previous infusion
- If adverse reactions occur, slow or stop the infusion - see under 'Further information'. Please also consult Medication Protocol: Management of Infusion Related patient reactions in nurse led infusion settings in GUH -available on Q pulse (CLN-NM-0118)

Further information

- Management of infusion related reactions: depending on the severity of the reactions, the infusion rate may either be **slowed or stopped.**
- Some cases of **acute renal failure** have been reported in patients receiving IVIG (particularly those containing sucrose as an excipient).
- Adequate hydration prior to infusion of IVIG is essential, urinary output and creatinine must be

monitored, and the concomitant use of loop diuretics should be avoided where possible.
- IVIG may interfere with responses to live vaccines - serological testing may be necessary- see SPC for details
- Contains glycine as an excipient
- IgA content is maximum 1800 microgam per ml
- IgG content is at least 96%

Storage

- Store below 25^{0}C, do not freeze

References

SPC November 2020

1: Communication with Dr Vincent Tormey,immunologist by email March 2011

(2) Department of Health 2011 Clinical Guidelines for the use of Intravenous immunoglobulinsÂ (2nd edition update)

Therapeutic classification

Intravenous immunoglobulin