Ciclosporin (Cyclosporin) Intravenous Infusion for Adults

Who can administer

May be administered by registered competent doctor or nurse/midwife

Important information

- See **monitoring** requirements
- There are numerous important **interactions** - check BNF
- Must have access to facilities for managing hypersensitivity reactions including **anaphylaxis**- due to polyethoxylated castor oil
- Dose adjustments needed in **renal** impairment- specialist review required
- **Low adsorption giving set and bag** required
- **If switching from oral to iv consult specialist team e.g. nephrology** as dose modification and risk assessment required

Available preparations

Sandimmun 50mg per 1ml ampoule

Reconstitution

Already in solution

Draw up using a 5 micron filter needle

Dilute further prior to administration

Infusion fluids

Sodium chloride 0.9% or Glucose 5% (Braun ecoflac or Macroflex containers - low adsorption)

Methods of intravenous administration

IMPORTANT for all intravenous routes of administration:

- Incompatible with PVC - a low adsorption infusion bottle (Braun ecoflac, or Baxter Viaflo) and a low adsorption giving set (e.g. Baxter VMC9606, or Braun 8700110SP) must be used
- The low adsorption set may be obtained from pharmacy
- Alternatively, a syringe pump and a low adsorption administration set (e.g Vygon Lectro-spiral 1155.80 or Braun Original Perfusor - Leitung PE 8723060) can be used

Intermittent intravenous infusion (administer using an electronically controlled infusion device)

- **Used in early post-transplantation stage, or if oral therapy not possible e.g. post-surgery, or during episodes of GI disturbances**
- Add required dose to a suitable volume of infusion fluid and administer over 2 to 6 hours (this infusion time may be used for any dose)

- The dose must be diluted between 1:20 to 1:100 to give a final concentration of between 0.5 and 2.5mg/ml
- **Example (using 50mg/1ml amps)**
- 50mg (1ml) in 20 to 100ml of infusion fluid
- 100mg (2ml) in 40 to 200ml of infusion fluid
- 200mg (4ml) in 80 to 400ml infusion fluid
- Mix well after addition to infusion fluid
- The residual volume in the infusion line must be flushed through at the same rate to avoid significant underdosing

Continuous intravenous infusion (administer using an electronically controlled infusion device)

- **Used for the treatment of Ulcerative colitis (unlicensed)**
- A continuous 24 hour infusion is used (ref 1,2)
- Mix well after addition to infusion fluid

Dose in adults

Temporary conversion of oral to intravenous therapy

- The total daily intravenous dose is approximately **one-third** of the total daily oral dose
- Oral dosing should commence as soon as possible
- Consider specialist advice- consult transplant team

Transplantation and autoimmune disorders

- Specialist advice should be taken before using this product
- For transplantation, various dosing regimens are used in specialist centres and higher doses are used initially
- Use IV route only if oral dosing not possible or if absorption is unreliable e.g. due to GI disturbance
- Dose reduction is recommended if a sustained rise in serum creatinine occurs - **consult with transplant team** before making any dose adjustments

Ulcerative colitis

- This is an unlicensed indication.
- **Specialist advice** should be taken before prescribing this product.
- A dose of 2mg/kg over twenty-four hours has been used (1,2)

Renal impairment

- Seek specialist advice
- Rises in serum creatinine while on ciclosporin will require specialist review

Hepatic impairment

- Dose adjustment may be required in hepatic impairment - seek specialist advice

Monitoring

- Observe patient **continuously for at least 30 minutes** after starting the infusion and at frequent intervals thereafter
- Monitor **whole blood trough** level routinely in transplant patients, and following co-administration of interacting drugs, otherwise only if non-compliance suspected
- Need to state dose regimen, time and date of both last dose and of sample time on blood specimen
- There are very few guidelines on the desired blood levels - this is because the required range can

depend on the indication, time post- transplant (if being used for this indication), and on the assay methods used to test samples. Seek specialist advice.
- Markedly nephrotoxic, check baseline serum creatinine then monitor frequently
- Need to distinguish between rejection and ciclosporin induced nephrotoxicity in transplant patients if serum creatinine rises.
- During the concomitant use of a drug that may exhibit nephrotoxic synergy, closely monitor renal function
- Monitor liver function, blood pressure, serum potassium, magnesium and lipids

Further information

- Must be given in a non-PVC bag (e.g. Ecoflac or Macroflex) and giving-set to prevent leaching of toxic DEHP from PVC
- Check for numerous interactions, including St. John's Wort - specialist advice required if interacting drug added
- Vaccinations may be less effective; avoid live attenuated vaccines

Storage

Store below 25^{0}C

References

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1: Long term results of low-dose intravenous ciclosporin for acute severe ulcerative colitis. Rayner C.K et al Aliment Pharmacol Ther 2003; 18: 303-308

2: Randomised double blind comparison of 4mg/kg vs 2mg/kg Intravenous ciclosporin in severe ulcerative colitis Assche et al, Gastroenterology 2003;125:1025-1031

Therapeutic classification

Immunosuppressant