MONOGRAPH

Methylprednisolone Sodium Succinate

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring

DRUG CLASS

Methylprednisolone sodium succinate is a systemic corticosteroid with minimal mineralocorticoid activity.(1)

Methylprednisolone ACETATE is NOT covered in this monograph.
Methylprednisolone ACETATE should NOT be given intravenously.

INDICATIONS AND RESTRICTIONS

- Methylprednisolone sodium succinate is indicated for inflammatory disorders including but not limited to: severe asthma, acute transplant rejection, multiple sclerosis, autoimmune or inflammatory diseases including juvenile idiopathic arthritis (JIA), Kawasaki disease, lupus, nephrotic syndrome and ulcerative colitis.(2, 3)
- At PCH methylprednisolone is included in renal, oncology, gastroenterology and neurology protocols.

Methylprednisolone sodium succinate is unrestricted on Formulary One

CONTRAINDICATIONS

- Hypersensitivity to methylprednisolone sodium succinate or any component of the formulation.[4]
- The Solu-Medrol Act-O-Vial 40 mg contains lactose monohydrate produced from cow's milk and is contraindicated in *patients with a known or suspected hypersensitivity to cow's milk or its components or other dairy products.*[3]
- Systemic fungal infection (except when methylprednisolone sodium succinate is being used to control drug reactions).[4]
- Administration of live virus vaccines - only contraindicated when immunosuppressive doses of methylprednisolone administered.[3, 4]
- IM administration in immune thrombocytopenia/idiopathic thrombocytopenic purpura.[3]
- Intrathecal administration.[4]
- Methylprednisolone formulations containing benzyl alcohol preservative are contraindicated in premature infants ("gasping syndrome" may occur.) Do not give medications containing benzyl alcohol to neonates.[5]

PRECAUTIONS

- Avoid in active systemic infections, unless part of a specific guideline.
- Avoid in latent tuberculosis, peptic ulcer disease, diabetes, hypertension, heart failure, psychiatric disorders, glaucoma, osteoporosis, myasthenia gravis, phaeochromocytoma.[3, 6]
- May affect growth velocity; monitor growth routinely in paediatric patients.[3]

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- Methylprednisolone sodium succinate 500 mg (Solu-Medrol®) vial
- Methylprednisolone sodium succinate preservative free 125 mg (Solu-Medrol Act-O-Vial®)
- Methylprednisolone sodium succinate preservative free 40 mg (Solu-Medrol Act-O-Vial®)

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Autoimmune or inflammatory disease:

Please note some doses are mg/kg and others are mg/m^2

Dose will depend on the condition and its severity.

4 weeks – 18 years:

- IV: 0.5 – 4 mg/kg daily in 2 – 4 divided doses (usual adult dose 10 – 500 mg daily).[2]

Pulse Therapy may be more suitable for some conditions (e.g. systemic Juvenile Idiopathic Arthritis (JIA), Kawasaki Disease, Inflammatory Bowel Disease):

4 weeks – 18 years:

- IV: 15 – 30 mg/kg (maximum 1000 mg) once daily for 3 days or on alternate days for 3 doses. Consultants can order further daily pulses if clinically required. Pulse can be repeated after 1 week; several pulses may be required to reduce disease activity.(2)

Kawasaki disease:

Please see the following guideline Kawasaki Disease Diagnosis And Management

Acute demyelination:

4 weeks – 18 years:

Where symptoms interfere with daily functioning:

- IV: 20 – 30 mg/kg/day (maximum 1000 mg) once daily for 3 - 5 days. Incomplete response may require subsequent oral steroid tapering dose. A repeat course of IV methylprednisolone or intravenous immunoglobulin may be used if clinically indicated.(3)

Inflammatory bowel Disease

Crohn's Disease Initial therapy (induction)

- IV: 1 mg/kg up to 50 mg once daily. Generally given for 3 to 7 days.(3)

Ulcerative colitis

Initial therapy (acute severe ulcerative colitis)

- IV: 1 mg/kg up to 50 mg once daily. Generally given for 3 to 5 days.(3)

Acute transplant rejection (solid)

Dosage depends on the type of transplant and immunosuppressive regimen.

Consult specialist. The following doses have been used:

4 weeks – 18 years:

- IV: 10 – 20 mg/kg or 400 – 600 mg/m^2 (maximum 1000mg) once daily for 3 days (usual adult dose 250 mg – 1000 mg once daily for 3 – 5 days.(2)

Graft vs Host Disease (haematopoietic stem cell transplant)

Refer to Transplant and Cellular Therapy (TCT) Graft vs. Host Disease Standard Operating Procedure and consult with Transplant/Oncology Physician. Therapy should only be initiated under the guidance of a Transplant Physician.

Suggested starting dose 2 mg/kg IV daily in divided doses.(8)

Lupus Nephritis

The following doses have been used:

4 weeks – 18 years:

- IV: 10 – 30 mg/kg once daily or on alternate days (maximum 1000 mg per dose) for up to 3 doses.
- High-dose "pulse" therapy: 30 mg/kg/dose or 600 - 1000 mg/m^2/dose (maximum dose 1000 mg) once daily for 3 days.[3]

NOTE: Methylprednisolone sodium succinate should be prescribed on the paediatric Hospital Medication chart (pHMC).

Renal impairment:

- Corticosteroids should be used with caution in renal impairment although it is thought no dosage adjustment required.[4]

Hepatic impairment:

- It is thought no dosage adjustment is required, although use with caution in patients with cirrhosis due to an enhanced effect.[4]

RECONSTITUTION & ADMINISTRATION

Where possible contact Pharmacy Compounding Service (PCS) to prepare the infusion.

- 500 mg vials: Reconstitute with 5 mL of water for injections to make a concentration of 100 mg/mL. The powder takes time to dissolve.
  - Do not use solutions that are cloudy or contain particles. Ensure that vial is completely dissolved before use.[1]
  - Dilute the dose further with a compatible fluid prior to intravenous administration.
- Act-O-Vial®: Tap to ensure the powder is at the base of the vial. Place vial on a flat surface and press down firmly on the plastic activator to force diluent into the lower powder compartment. Gently turn the vial upside down a number of times. Do not shake.[1]

Intravenous:

Dose	Volume*
< 500 mg	Dilute to 10 mg/mL
500 - 1000 mg	50 mL or 100 mL (to approximately 10 mg/mL)

*Doses < 2 mg/kg can be injected over at least 5 minutes

*Doses > 2 mg/kg must be infused over at least 30 minutes.[1, 9]

*Smaller volumes may be used in fluid restricted patients (maximum recommended concentration is 20 mg/mL).[1]

Administration Precautions[1]

- Rapid administration of large IV doses (i.e. doses greater than 500 mg given in less than 10 minutes) may cause cardiac arrhythmias, circulatory collapse and/or cardiac arrest.
- Intramuscular: Inject doses up to 250 mg deep into a large muscle e.g. gluteal muscle. Refer to Intramuscular (IM) Injections.
- Subcutaneous: Not recommended.

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids: Glucose 5%, glucose 5% in sodium chloride 0.9%, sodium chloride 0.9%.[1]

Compatible at Y-site: Amifostine, anidulafungin, atracurium, aztreonam, bivalirudin, cefalotin, cefazolin, ceftaroline fosamil, ceftazidime, ceftriaxone, ciclosporin, clindamycin, defibrotide, dexmedetomidine, dopamine, ephedrine sulfate, furosemide, gentamicin, glyceryl trinitrate, granisetron, linezolid, metoclopramide, metronidazole, morphine sulfate, paracetamol, pethidine, piperacillin-tazobactam (EDTA-free), remifentanil, sodium bicarbonate, suxamethonium, tobramycin, verapamil.[1]

Only commonly used drugs are listed below. This is not a complete list of incompatible drugs. Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

INCOMPATIBLE drugs: Calcium chloride, calcium folinate, calcium gluconate, caspofungin, cefotaxime, cefoxitin, ciprofloxacin, cisatracurium, filgrastim, foscarnet, ganciclovir, haloperidol lactate, hydralazine, isavuconazole, magnesium sulfate, mycophenolate mofetil , ondansetron, palonosetron, pentamidine, potassium chloride, promethazine, propofol, protamine, pyridoxine, rocuronium, thiamine, tigecycline, vancomycin, vecuronium.[1]

MONITORING

- Monitor patient's blood pressure and pulse at baseline, then every 15 minutes for the infusion duration.
- Repeat every 30 minutes for two hours on completion of the infusion.[4]

ADVERSE EFFECTS

Common: adrenal suppression, infection, sodium and water retention, oedema, hypertension, hypokalaemia, hyperglycaemia, diabetes, dyslipidaemia, osteoporosis, fractures, increased appetite, dyspepsia, delayed wound healing, skin atrophy, bruising, acne, facial flushing, hirsutism, growth retardation in children, myopathy, muscle weakness and wasting, fat redistribution (producing cushingoid appearance), weight gain, menstrual irregularity, amenorrhoea, psychiatric effects (below), posterior subcapsular cataracts, skin and subcutaneous tissue atrophy at injection site (may be associated with hypopigmentation).

Infrequent: osteonecrosis, particularly of the femoral and humeral heads, ocular hypertension, glaucoma.

Rare: peptic ulceration, hypersensitivity reactions, tendon rupture (especially of the Achilles tendon), central serous chorioretinopathy, fat deposition around spinal cord, Psychiatric effects - Include euphoria, hypomania, depression, disturbances of mood, cognition, sleep and behaviour. Delirium or psychosis are less common.[6]

STORAGE

Vial: store below 25 °C. Protect from light.[1]

Reconstituted solution: stable for up to 24 hours below 25 °C.[1]

Infusion solution: solutions in sodium chloride 0.9% are stable for up to 24 hours below 25 °C.[1]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **Methylprednisolone Sodium Succinate**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

References

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