MONOGRAPH

OCTREOTIDE

Scope (Staff):	Medical, Pharmacy, Nursing, Anaesthetic Technicians
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

Octreotide is a synthetic octapeptide analogue of naturally occurring somatostatin which has similar pharmacological effects but a prolonged duration of action.

Octreotide inhibits the secretion of serotonin and the gastroenteropancreatic peptides: gastrin, vasoactive intestinal peptide, insulin, glucagon, secretin, motilin and pancreatic polypeptide, and of growth hormone.[1]

Decreases splanchnic arterial blood flow.[1]

INDICATIONS AND RESTRICTIONS

- Persistent hyperinsulinaemic hypoglycaemia[2]
- Chylothorax[3]
- Graft-versus-host disease (GVHD) - induced diarrhoea[3]
- Control of bleeding of gastro-oesophageal varices[2]
- Short bowel syndrome[3]
- Hypoglycaemia due to sulfonylurea overdose[4]
- Cushing's syndrome[3]
- Acromegaly[4]
- Antidote for sulfonylurea poisoning or overdose[3]

CONTRAINDICATIONS

- Hypersensitivity to octreotide or any component of the formulation.

PRECAUTIONS

- May affect glucose regulation. Insulin and oral hypoglycaemia medication requirements may change in patients with type 1 diabetes mellitus, review and adjust accordingly.[1]
- Long term therapy
  - May alter absorption of dietary fats. Monitor for pancreatitis.[3]
  - Incidence of cholelithiasis or biliary sludge increases with therapy ≥ 12 months. Monitor liver function in patients on long term therapy.[3]
  - Can suppress secretion of thyroid stimulating hormone (TSH). Monitor thyroid function for hypothyroidism during long term treatment.[5]
- Adequate contraception is recommended for female patients of childbearing potential.[1]
- Avoid abrupt withdrawal of subcutaneous octreotide due to risk of biliary colic and pancreatitis.[6]

FORMULATIONS

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

- Ampoule (short acting): 100 micrograms/mL; 500 micrograms/mL[1]
- Modified release (long acting) injection (Sandostatin LAR®): 10 mg. 20 mg, 30 mg[1]

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Persistent hyperinsulinaemic hypoglycaemia:

Subcutaneous: Suitable for ≥ 4 weeks to 18 years:

- Intermittent subcutaneous injections: 1-2 microgram/kg every 6 hours. Titrate up to 7 microgram/kg every 6 hours.[2]
- Continuous subcutaneous infusion: 5 microgram/kg/day, titrate up to a usual maximum of 40 microgram/kg/day.[2,3,4]

Intramuscular injection (IM)[9] using the modified release (long acting) formulation Sandostatin LAR®: Suitable for children > 1 year of age under the supervision of an endocrinologist:

- Calculate patient's cumulative 31-day subcutaneous dose, which will equal the monthly IM dose.
- Administer this dose every 4 weeks.
- Continue with subcutaneous octreotide therapy for 2 months after starting the IM long-acting formulation (the first 2 IM depot doses) then discontinue subcutaneous dosing at the time of the third IM dose.
- Monitor patient closely for hypoglycaemia while receiving both IM (long-acting) and subcutaneous octreotide.

Chylothorax:

≥ 4 weeks to 18 years:

- Continuous IV infusion: 0.3-10 microgram/kg/hour titrated to response[3,5]
- Subcutaneous: 10 microgram/kg 8 hourly. Can increase up to 40 microgram/kg/DAY[5]

Diarrhoea:

≥ 4 weeks to 18 years:

- Continuous IV infusion: 1 microgram/kg bolus followed by 1 microgram/kg/hour infusion[3,4]
- IV/Subcutaneous: 1-10 microgram/kg/dose (max 500 micrograms) every 8-12 hours, titrate according to response[3,4]

Gastro-oesophageal bleeding:

≥ 4 weeks to 18 years:

- Continuous IV infusion: 1-2 microgram/kg IV bolus (maximum 50 micrograms) followed by 1-5 microgram/kg/hour continuous IV infusion (maximum 50 micrograms/hour).[4]
    - Titrate infusion rate to response every 8 hours if no effect[4]
    - Taper dose by 50% every 12 hours when no active bleeding occurs for 24 hours, may discontinue once dose is 25% of initial dose[3,4]

Sulfonylurea poisoning/overdose:

≥ 4 weeks to 18 years

- Subcutaneous injection: 1 – 1.3 microg/kg/dose every 6 hours. Repeat as needed as per blood glucose concentration.[3]

Renal impairment:

Dosage adjustment may be required in patients receiving dialysis.[3] eGFR calculator

Hepatic impairment:

Dosage adjustment may be required in patients with established cirrhosis.[3]

RECONSTITUTION & ADMINISTRATION

Reconstitution - Intramuscular injection (Sandostatin LAR®)

1. Remove the injection kit from the refrigerator, allowing 30 minutes for it to come to room temperature.
2. Remove the vial cap.
3. Place the vial adaptor on top of the vial and push it down until it is fixed in place (this confirmed by the sound of an audible "click").
4. Remove the cap from the diluent-containing syringe and affix it to the vial adaptor.
5. Inject the diluent slowly into the vial.

Allow the vial to stand for 5 minutes then swirl it gently for 30-60 seconds, to produce a milky, uniform suspension. Do not shake or invert the vial. Use immediately. As the vial contains overage a small amount of suspension will remain on the wall and bottom of the vial.[1]

Reconstitution of the short acting ampoule is not required

Administration:

It is preferable for intravenous and intermittent subcutaneous octreotide orders to be made by PCH Pharmacy Compounding Services (PCS)

Continuous intravenous infusion (short acting formulation only):

Patient's Weight	Concentration (in sodium chloride 0.9%)	Notes
10 kg or less	300 micrograms in 30 mL (10 micrograms/mL)	In a 10 kg patient, 1 microg/kg/hour = 1 mL/hr
Above 10 kg	2.5 mg in 50 mL (50 micrograms/mL)	In a 20 kg patient, 1 microg/kg/hour = 0.4 mL/hr

Note: Patient's on high infusion rates may be prescribed a higher concentration preparation of 10 mg in 50 mL (200 micrograms/mL).

Intermittent intravenous injection (short acting formulation only):

- Dilute to 5-250 microgram/mL using a suitable compatible fluid and infuse over 15-30 minutes.[7]
- May be administered undiluted over 3 minutes in emergency situations.[8]
- Allow solution to come to room temperature before administration.[5]

Subcutaneous injection (short acting formulation only): Rotate injection site. Allow solution to come to room temperature before administration.

Use the smallest volume to reduce injection site pain:

- Doses ≥ 75 micrograms should be drawn up using the neat 500 microgram/mL ampoule
- Doses 50 – 74 micrograms, dilute the 500 microgram/mL ampoule to 250 micrograms/mL in sodium chloride 0.9% (preferred diluent)
- Doses < 50 micrograms, should be drawn up using the neat 100 micrograms/mL ampoule

Subcutaneous infusion (Only under the supervision of an endocrinologist) Dose can be delivered as the neat 500 microgram/mL solution via an insulin pump and subcutaneous catheter. Careful dose conversion is required. A stable 24 hour dose can be prescribed on the WA Paediatric Hospital Medication Chart, variable dosing should be prescribed on the Parenteral Fluid Therapy Order Chart MR828.00

Intramuscular injection (Sandostatin LAR® only): Inject deep into gluteal muscle. Alternate sides for subsequent injections.[8]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

Sodium chloride 0.9% (preferred diluent)[7]

Glucose 5% [7]

Compatible at Y-site:

Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

INCOMPATIBLE drugs:

Cyclizine, micafungin[8]

MONITORING

Ultrasound examination of the gallbladder is recommended prior to commencing therapy and every 6-12 months thereafter.[1]

Obtain baseline thyroid function prior to initiation and periodically after treatment for chronic therapy, as requested by the treating consultant.[3]

For diabetic patients, monitor blood glucose level and assess diabetic treatment following initiation of octreotide.[3]

For long term treatment, monitor vitamin B_{12} level and cardiac function (heart rate, ECG)[3]

For patients with impaired hepatic function (liver cirrhosis), consider adjusting the maintenance dose of short-acting formulation.[1]

Monitoring for patients treated for Acromegaly:

- Initial Treatment

  1) Short acting formulation: To evaluate responsiveness to therapy, measure serum growth hormone (GH) every 1-4 hours for 8-12 hours post dose, or a single measurement of serum insulin-like growth factor (IGF-1) 2 weeks after initiation or after dose adjustment.[3]

  2) Long acting formulation: At 3 months (prior to next dose), measure serum GH and IGF-1.[3]

- Maintenance Treatment

  1) Every 3-6 months, measure serum GH and IGF-1.[3]

Long acting formulation: After 6 months, if clinical and biological response is inadequate, consider to discontinue treatment.[1]

ADVERSE EFFECTS

Common: Abdominal pain, flatulence, nausea, vomiting, diarrhoea, constipation, steatorrhoea, headache, fatigue, dizziness, hyperglycaemia, hypoglycaemia, cholelithiasis (after long term treatment), hyperbilirubinaemia, alopecia, pruritis, transient local reaction at injection site, dyspnoea, bradycardia, gall stones (often asymptomatic).[1, 6]

Rare: Hypothyroidism, pancreatitis, hepatic dysfunction, allergic reactions.[6]

STORAGE

Refrigerate, do not freeze.[8]

Protect from light.[8]

Ampoule: Unopened product may be stored for up to two weeks at or below 25^{o}C.[8]

Modified release injection: Can be stored below 25^{o}C on the day of injection before reconstitution.[8]

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 **octreotide**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

NICU protocol - Octreotide

Intramuscular Injection - Clinical Practice Manual

Subcutaenous InsuflonTM Catheter - Clinical Practice Manual

Subcutaneous Injections – Clinical Practice Manual

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