MONOGRAPH

OMALIZUMAB

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	Monitoring	Adverse Effects

DRUG CLASS

Anti-IgE monoclonal antibody.[1]

oMALizumab may be confused with oCRELizumab. Double check medication.

INDICATIONS AND RESTRICTIONS

- Severe allergic asthma.[1]
- Chronic spontaneous urticaria.[1]
- The prescribing of omalizumab must be in accordance with the PBS Section 100 Highly Specialised Drug Program prescribing guidelines.
- Omalizumab is approved for the following non-PBS indication: management of venom desensitisation in patients who experience anaphylaxis.
- All other non-PBS indications require an Individual Patient Approval (IPA) from the hospital's Drug and Therapeutics Committee.

CONTRAINDICATIONS

Hypersensitivity to omalizumab or any component of the formulation.[2]

PRECAUTIONS

- Do not abruptly discontinue systemic or inhaled corticosteroid upon initiation of omalizumab.[2,3]
- Patients with a history of systemic neoplastic disease and patients with a high risk for malignancy.[3]
- Patients at risk of parasitic (helminth) infections.[2,3]
- Patients with thrombocytopenia or with a history of thrombocytopenia.[4]

FORMULATIONS

Listed below are products available at Perth Children's Hospital (PCH). Other formulations may be available, check with pharmacy if required:

- 75 mg/0.5 mL and 150 mg/1 mL prefilled syringes (Xolair®)

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Severe allergic asthma:

Dosage and dosage frequencies are determined by baseline serum total IgE level (units/mL) and measured body weight (kg).[1-3]

- 6 – 18 years: 75 – 375 mg administered subcutaneously every 2 to 4 weeks.[2,3]

Chronic spontaneous urticaria:

- 12 – 18 years: 150 – 300 mg administered subcutaneously every 4 weeks.[1-3]

Renal impairment:

- No dosage adjustment is required in renal impairment.[3]

Hepatic impairment:

- No dosage adjustment is required in hepatic impairment.[3]

ADMINISTRATION

- Administer by subcutaneous injection: Inject over 5 to 10 seconds into the upper arm, abdomen or thigh.[5]
- Do NOT administer by intramuscular or intravenous routes.[5]
- The solution should be clear and colourless to pale brownish-yellow.[3,5]
- Keep the syringe in the carton and allow it to reach room temperature for at least 30 to 45 minutes prior to injection.[3,5]
- Doses greater than 150 mg should be divided over more than 1 injection site. Each injection site should be separated by ≥ 4cm.[1,2]

MONITORING

Immediate Post-Dose Monitoring

- Omalizumab can cause serious hypersensitivity reactions or anaphylaxis.[2,3]
- The first THREE doses **must** be given by or under the supervision of a healthcare professional.[5]
    - In asthma, patients must be monitored for 2 hours following the first **THREE** doses.[2,3]
    - In urticaria, patients must be monitored for 2 hours following the **FIRST** dose.[6]
- Monitoring duration may be reduced to 30 minutes for subsequent injections unless advised otherwise by the treating consultant.[1,2]
- Monitor blood pressure, pulse, respiratory rate and oxygen saturation prior to administration of injection and then regularly during monitoring period.

****Care must be escalated immediately and a "Code Blue" or "anaphylaxis page via Vocera" initiated whenever anaphylaxis is suspected.****

- After the first THREE doses, patients or caregivers may self-inject omalizumab at home if they have had adequate training and the treating consultant determines that it is appropriate.[3]

Long-Term Monitoring

- In asthma, monitor baseline total serum IgE, forced expiratory volume in one second (FEV1), peak flow, and/or other pulmonary function tests.[2]
- Monitor all patients for signs of infection.[2]

ADVERSE EFFECTS

- Hypersensitivity/anaphylactoid reactions (angioedema of the throat or tongue, bronchospasm, hypotension, syncope, and urticaria) may occur, usually within 2 hours, but some have occurred up to 4 days post injection.[2,3]

Instruct patients and parents/carers on the signs and symptoms of anaphylaxis.

- Clinicians may consider prescribing an adrenaline (epinephrine) autoinjector on discharge with education on how to use it for select patients with risk factors for anaphylaxis or with limited access to medical facilities.

Common: Injection site reactions (pain, swelling, itching and redness), pharyngitis, sinusitis, rash, headache, musculoskeletal pain, fever.[2,3]

Infrequent: Alopecia, urticaria, upper abdominal pain, cough, dizziness, fatigue, nausea.[2,3]

Rare: Angioedema, antibody formation, new primary malignancy, syncope.[2,3]

STORAGE

Refrigerate between 2 to 8°C. Do not freeze.[5]

Syringe can be kept at room temperature for up to 48 hours.[5]

Protect from light.[5]

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

Related CAHS internal policies, procedures and guidelines

Subcutaneous Injections – Clinical Practice Manual

Allergy and Adverse Drug Reaction Management – CAHS Policy Manual

References

1. AMH Children's Dosing Companion. Adelaide: Australian Medicines Handbook Pty Ltd; 2024 [cited October 2024]. Available from: Omalizumab - AMH Children's Dosing Companion (health.wa.gov.au).
2. UpToDate. Omalizumab: Pediatric Drug Information. Lexicomp; 2024 [cited October 2024]. Available from: Omalizumab: Drug information - UpToDate (health.wa.gov.au)
3. Omalizumab. Clinical Pharmacology powered by ClinicalKey. Philadelphia (PA): Elsevier. 2024 [cited October 2024]. Available from: Omalizumab Monograph - Clinical Pharmacology (health.wa.gov.au)
4. Australian Medicines Handbook. Adelaide: Australian Medicines Handbook Pty Ltd; 2024 [cited January 2025]. Available from: Omalizumab - Australian Medicines Handbook (health.wa.gov.au)
5. Society of Hospital Pharmacists of Australia. Australian Injectable Drugs Handbook: Health Communication Network; 2024 [cited October 2024]. Available from: AIDH - OMALIZUMAB (health.wa.gov.au)
6. British Association of Dermatologists. Omalizumab Patient Information Leaflet; 2023 [cited January 2025]. Available from: British Association of Dermatologists (bad.org.uk)

Useful resources (including related forms)
Chronic Spontaneous Urticaria (CSU) Guidelines - Australasian Society of Clinical Immunology and Allergy (ASCIA)

This document can be made available in alternative formats on request for a person with a disability.

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