Specialised Medication - Abatacept for ADULT Patients Guideline

1. Guiding Principles

Provides guidance for prescription and administration of intravenous abatacept for adult patients.

This guideline must be used in conjunction with the associated mandatory MR173e WACHS Specialised Medication - Abatacept Pre-Infusion Checklist.

Information contained in this guideline is specific for Orencia®.

This infusion may only be administered when there is a doctor who is:

- familiar with this guideline
- aware of the patient receiving the infusion
- credentialed and appointed to the hospital site where the infusion is being administered
- willing and able to respond in the event of an emergency in the absence of a dedicated Medical Emergency Response (MER) team.

2. Guideline

Abatacept is a co-stimulation modulator for antigens on T lymphocytes. It is an anti-inflammatory modifier that achieves its effect by down regulating T cell activation.[1]

2.1 Presentation[2]

Powder for intravenous infusion 250 mg in a single use 15 mL vial with silicone free, latex free disposable syringe.

Alternatively, some WACHS Pharmacy Departments may purchase infusions prepared by sterile manufacturing facilities.

2.2 Indication[3]

Availability of abatacept is currently restricted to indications listed on the PBS on presentation of an approved PBS authority prescription.

- Rheumatoid arthritis

2.3 Contraindications[1,2]

- Hypersensitivity to abatacept or any of its excipients.
- Serious or untreated infections (sepsis, abscess, hepatitis B, active TB (before completing TB treatment), opportunistic infections)

2.4 Precautions[1,2]

- Concomitant use of abatacept with other cytokine modulators is not recommended.
- Live vaccines should not be given concurrently with abatacept or within three months of its discontinuation.
- May worsen respiratory symptoms of Chronic Obstructive Pulmonary Disease.
- Consider the increased risk of peri-operative infections.
- Pregnancy. Limited data. Australian category C.
- Breastfeeding is not recommended.

2.5 Dosage[1,2]

Adults: IV dosing in Rheumatoid Arthritis:

Adult Patient's Weight	Dose	Frequency
Less than 60 kg	500 mg	0, 2, 4, then 4 weekly
60 to 100 kg	750 mg	0, 2, 4, then 4 weekly
Greater than 100 kg	1000 mg	0, 2, 4, then 4 weekly

2.6 Administration[2,4,5]

Specific Considerations for Handling:

- Prepare using aseptic technique.
- Personal Protective Equipment (PPE) - A respirator mask (N95) and protective eye wear should be worn during preparation. These PPE should also be worn during administration processes for IV formulations where the dis/connecting of administration lines may present a risk of aerosolisation, particularly with new or inexperienced staff.
- Closed system drug transfer devices are not required for the preparation of doses for administration but can be utilised by individual sites based on availability.
- All waste is to be handled as per standard procedures for parenterally administered agents.
- Avoid preparation and handling if pregnant, breastfeeding or immunosuppressed

Dilute before use – For IV Infusion Only

2.6.1 Using the silicone free latex free disposable syringe supplied, reconstitute the 250 mg vial for IV infusion with 10mL Water for Injection BP by directing the stream of water down the wall of the vial. Do not use if the vacuum is not present.

2.6.2 Rotate gently until the contents are completely dissolved – **Do Not Shake**.

2.6.3 The vial should be vented with a needle to dissipate any foam that may be present.

2.6.4 After reconstitution, the concentration of abatacept in the vial will be 25mg/mL. The prepared solution should be clear and colourless to pale yellow and should be further diluted immediately (see following steps).

2.6.5 Calculate the volume of the reconstituted abatacept to provide the prescribed dose.

2.6.6 Withdraw and discard the volume calculated in step 5 from a 100mL sodium chloride 0.9% non-pyrogenic bag.

2.6.7 Add the required dose of abatacept to the sodium chloride 0.9% bag, using the silicone free latex free disposable syringe provided and gently mix. Discard any remaining solution.

2.6.8 **Do Not Use** if there is any visible particulate matter or the solution is discoloured.

2.6.9 **Do Not** co-administer with any other IV medication.

2.6.10 **Do Not Use** any syringe other than the silicone free, latex free syringes provided with the product.

2.6.11 Infuse using an infusion set and a sterile, non-pyrogenic, low protein binding filter (pore size 0.2 to 1.2 micron) over 30 minutes.

2.7 Storage[2]

- Lyophilized powder, ampoules and syringes: store between 2-8 deg.C.
- Do not freeze. Protect from light, store in original package.
- Diluted infusion solution should be infused immediately but may be stored at 2 to 8 deg C for not more than 24 hours.
- Do not freeze.

2.8 Infusion reactions[2,6]

2.8.1 'Mild' infusion reactions

Hypersensitivity reactions with the infusion of abatacept are uncommon. Symptoms have been reported up to 24 hours after the infusion and include headache, nausea, dizziness and hypertension. In the event of a 'mild' infusion reaction the prescriber should be contacted and the patient managed on an individual case basis.

2.8.2 'Severe' infusion reactions/ anaphylactic reactions

These reactions involve symptoms such as (but not limited to): Anaphylaxis, hypo/hypertension, chest pain, dyspnoea, swelling, severe pruritis

The infusion should be **stopped** immediately and the prescriber informed. Patients should be managed on an individual case basis with therapy including (but not limited to) adrenaline, antihistamines, glucocorticoids (eg. dexamethasone), intravenous fluids, vasopressors, oxygen, bronchodilators and paracetamol.

Patient management should be:

- escalated according to the observation and response chart (ORC) criteria
- in accordance with Adverse Drug Reaction section of the WACHS Medication Prescribing and Administration Policy.

For guidance on the management of anaphylaxis, refer to the ASCIA Guidelines – Acute management of anaphylaxis.

Where applicable the WACHS doctor should discuss this event with the referring specialist.

2.9 Monitoring requirements [6]

- Minimum physiological observations to be documented pre infusion, mid infusion, post infusion and as clinically indicated during the infusion based on patient response (eg light-headedness, flushing).

3. Roles and Responsibilities

Nurse Unit Manager / Senior Nursing Staff

- Receiving valid referral and documentation including a valid PBS prescription as required from the prescribing consultant or other treating doctor
- Inform the prescriber, if external to the hospital, that the infusion has been administered and any related outcomes (e.g. adverse events).

The Medical Officer

- Completes all treatment and duties within scope of practice.

The Registered Nurse

- Complete all nursing duties for the patient within scope of practice including escalation of care as per AORC

4. Compliance

Failure to comply with this policy document may constitute a breach of the WA Health Code of Conduct (Code). The Code is part of the Integrity Policy Framework issued pursuant to section 26 of the *Health Services Act 2016* (WA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all policies is mandatory.

5. Records Management

All WACHS clinical records must be managed in accordance with Health Record Management Policy.

6. Evaluation

Adverse events and clinical incidents relating to the administration of abatacept infusions are to be zero (0).

7. Standards

National Safety and Quality Health Service Standards
Clinical Governance Standard: 1.7, 1.10
Precenting and Controlling Healthcare Associated Infection Standard: 3.9
Medication Safety Standard: 4.3, 4.4, 4.7, 4.8, 4.11, 4.15
Comprehensive Care Standard: 5.10, 5.11
Communicating for safety Standard: 6.5
Recognising and Responding to Acute Deterioration Standard: 8.4, 8.5, 8.6.

8. Legislation

Medicines and Poisons Act 2014 (WA)
Medicines and Poisons Regulations 2016 (WA)

9. References

1. Australian Medicines Handbook Pty Ltd [Accessed: 18 March 2021]
2. MIMS Online [Accessed: 18 March 2021]
3. Pharmaceutical Benefits Scheme (PBS) [Accessed: 18 March 2021]
4. Australian Injectable Drugs Handbook [Accessed: 18 March 2021]
5. Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel. (May 2013) Western and Central Melbourne Integrated Cancer Services – project working group.
6. Department Pharmacy. Day infusion information - patient monitoring, handling Mabs, management of infusion reactions. Bunbury, Western Australia: WACHS-SW; Page last updated 24/8/2016

10. Related Forms

MR173E WACHS Specialised Medication - Abatacept Pre-Infusion Checklist
MR140A Adult Observation and Response Chart

11. Related Policy Documents

WACHS Aseptic Technique Policy
WACHS High Risk Medications Procedure
WACHS Medication Handling and Accountability Policy
WACHS Medication Prescribing and Administration Policy
WACHS Safe Handling and Administration of Monoclonal Antibodies Guideline

12. Related WA Health Policies

MP 0053/17 WA Clinical Alert (Med Alert) Policy
MP 0131/20 WA High Risk Medication Policy

13. WA Health Policy Framework

Clinical Governance, Safety and Quality Policy Framework

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

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