MONOGRAPH

Baricitinib Monograph - Paediatric

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

DRUG CLASS

Cytokine modulator – Janus kinase 1 and 2 (JAK) inhibitor.[1]

INDICATIONS AND RESTRICTIONS

Contact ChAMP or ward Pharmacist for advice on the eligibility and procurement of baricitinib.

An Individual Patient Application (IPA) MUST be approved by the CAHS Drug and Therapeutics Committee (DTC) prior to commencing treatment.

- Baricitinib is indicated for use in hospitalised patients 2 years and older with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection [COVID-19] requiring ventilation (invasive or non-invasive) AND with systemic inflammation (C-reactive protein (CRP) ≥75mg/L or rapidly rising) despite optimised dexamethasone therapy.[2]
- Baricitinib is also indicated for rheumatoid arthritis and moderate to severe atopic dermatitis in adults. These indications are non-formulary at PCH and also require an IPA.[1]

IV: Restricted (red) medication

ChAMP approval is required prior to prescription.

CONTRAINDICATIONS

- Hypersensitivity to baricitinib or any component of the formulation.
- Concurrent use of other cytokine modulators (e.g. TNF-alpha antagonists, rituximab or tocilizumab)[1]
- Baricitinib may reduce the number of white blood cells; do not start treatment if:
  - absolute neutrophil count of <1x10^9 cells/L OR
  - lymphocytes <0.5x10^9 cells/L OR
  - haemoglobin <80g/L.[1, 2]
- Baricitinib increases the risk of infection. The risk of infections is increased when used in patients on other immunosuppressants. Stop treatment if a serious or opportunistic infection develops.[1]
- Baricitinib should not be used in pregnancy. Sexually active adolescent females should use effective contraception during therapy and for a least a week after ceasing baricitinib.[1]

PRECAUTIONS

- Baricitinib may increase the risk of venous thromboembolism (VTE) in patients with additional risk factors for VTE. Monitoring for VTE should occur and consideration given for the use of VTE prophylaxis, especially in patients with severe COVID-19.[1-3]
- Live vaccines must not be given to people receiving baricitinib, vaccines may need to be delayed and consideration should be given if any live vaccines have been recently administered.[1, 2]

FORMULATIONS

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

- 2mg and 4mg tablets

Imprest location: Non-formulary - contact Pharmacy for access

DOSAGE & DOSAGE ADJUSTMENTS

- **Neonates and children <2 years old:** Not recommended
- **Children ≥ 2 years to <9 years:** 2mg once daily for a total duration of 14 days or until hospital discharge (whichever comes first).[2]
- **Children and adolescents ≥ 9 years:** 4mg once daily for a total duration of 14 days or until hospital discharge (whichever comes first).[2]

Renal impairment:

- eGFR calculator
- Dose reduction is required if eGFR is <60mL/minute.[1]

eGFR[2]	Children ≥ 2 years to <9 years	Children and adolescents ≥ 9 years
≥60mL/minute	Normal dose	Normal dose
≥30mL to <60 mL/minute	1mg once daily	2mg once daily
≥15mL to <30 mL/minute	Use not recommended	1mg once daily
<15 mL/minute, on dialysis, end-stage renal disease or acute kidney injury	Use not recommended	Use not recommended

Hepatic impairment:

- No dose adjustments required for mild or moderate impairment. Baricitinib is not recommended in patients with severe impairment as the use of baricitinib has not been studied in this population.[2, 4]

ADMINISTRATION

- **Do not crush or disperse the tablet if you are pregnant. In areas where all staff are in full COVID-19 personal protective equipment (PPE), the tablet may be cut in half using a tablet cutter.[5]**
- Baricitinib may be administered with or without food.[2, 4]
- *For children unable to swallow the tablets:*
  - Disperse the required dose in 5 to 10mL of water in an oral dispenser. The tablet may take up to 5 minutes to disperse.
  - Rinse the oral dispenser with 5mL of additional water to ensure the entire dose is given.[5]
- *For children with a nasogastric tube:*
  - Disperse the required dose in 30mL of water in an enteral syringe
  - Swirl gently until the tablet is dispersed. The tablet may take up to 5 minutes to disperse.
  - Rinse the syringe with an additional 15mL of water to ensure the entire dose is given.
- *For children with a gastrostomy tube:*
  - Disperse the required dose in 15mL of water in an enteral syringe
  - Swirl gently until the tablet is dispersed. The tablet may take up to 5 minutes to disperse.
  - Rinse the syringe with an additional 15mL of water to ensure the entire dose is given.
- Baricitinib is only slightly soluble; it may block tubes smaller than a size 12 French. Hold the enteral syringe horizontally and shake several times during administration to prevent blockage.[5]

MONITORING

Before treatment commences:

- Patients should be screened for hepatitis B and C and latent tuberculosis infection prior to starting baricitinib.[1]
- Patients should have baseline full blood picture conducted prior to commencement of baricitinib. Baricitinib should not be commenced in patients with:
  - absolute neutrophil count of $<1x10^9$ cells/L OR
  - lymphocytes $<0.5x10^9$ cells/L OR
  - haemoglobin <80g/L.[1, 2]

During therapy:

- Monitor patients for signs of infection (e.g. shingles)[1]
- Monitor patients liver function daily throughout therapy. In the event of an increase in alanine aminotransferase (ALT) or aspartate aminotransferase (AST) and drug-induced liver injury is suspected, treatment should be interrupted until drug induced liver injury is excluded.[2]

ADVERSE EFFECTS

Common: increased risk of infections, hypercholesterolaemia, thrombocytosis, nausea, abdominal pain, headache, increased creatine kinase.[1, 2]

Infrequent: venous thromboembolism, lymphopenia, anaemia, acne, vomiting, hypertriglyceridaemia, increased liver enzymes.[1, 2]

Rare: neutropenia[2]

STORAGE

- Store below 30°C.[4]

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

Related CAHS internal policies, procedures and guidelines
Antimicrobial Stewardship Policy
ChAMP Empiric Guidelines and Monographs
KEMH Neonatal Medication Protocols

References

1. Rossi S, editor. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2021.
2. Clinical Pharmacology [Internet]. Elsvier BV. 2021 [cited 06/01/2022]. Available from: http://www.clinicalpharmacology-ip.com.pklibresources.health.wa.gov.au/default.aspx.
3. National COVID-19 Clinical Evidence Taskforce. COVID-19 Clinical Care guidelines Australia2021 [Available from: https://app.magicapp.org/#/guideline/L4Q5An/section/L6q73j.
4. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2021. p. 1v. (various pagings).
5. Burridge N, Deidun D (editors). Australian Don't Rush to Crush Handboook. Therapeutic options for people unable to swallow solid oral medicines. 3rd edition ed. Collingwood: The Society of Hospital Pharmaciste of Australia; 2018.

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