MONOGRAPH

Itraconazole 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

⚠ HIGH RISK MEDICINE ⚠

QUICKLINKS		
Dosage/Dosage Adjustments	Administration	Monitoring

DRUG CLASS

Azole antifungal. [1-3]

Itraconazole is a High Risk Medicine.

INDICATIONS AND RESTRICTIONS

Itraconazole is indicated for the treatment of cutaneous and systemic fungal infections due to susceptible fungi (including yeasts, some Aspergillus species and *Sporothrix schenckii* [sporotrichosis]). Itraconazole may also be used as part of therapy for allergic bronchopulmonary aspergillosis (ABPA)[4, 5]

Itraconazole can also be used as prophylaxis for the above conditions in children and adolescents with specific immune deficiencies.[4]

Oral: Monitored (orange) antifungal

Itraconazole is indicated for use as per the indications stipulated in Formulary One. For any other use, phone approval must be obtained from ChAMP before prescribing as per the Children's Antimicrobial Management Program (ChAMP) Policy.

CONTRAINDICATIONS

- Hypersensitivity to itraconazole or any component of the formulation.[2, 5, 6]
- Itraconazole is a strong cytochrome CYP3A4 inhibitor. Potential drug interactions should be investigated before commencing treatment and before any changes are made to the medication profile of the patient.[2, 5]

PRECAUTIONS

The three available itraconazole formulations are NOT interchangeable.[2, 5]
ALL prescriptions should state the formulation and brand required.
PCH stocks only the Lozanoc® brand in the capsule formulation.
Itraconazole oral solution is the only liquid available and requires SAS approval.

- Itraconazole should be used cautiously in patients with:
  - A history of hepatic dysfunction or failure[5]
  - High risk of heart failure (including those with cardiac disease or ventricular dysfunction)[2, 7]
  - Chronic lung disease associated with pulmonary hypertension.[7]
  - Receiving treatment with negative ionotropic drugs (e.g. calcium channel blockers)[2, 5, 7]

Contact Pharmacy or refer to literature for further information.[3, 6, 7]

- Cystic fibrosis patients have large variations in pharmacokinetics, consider alternatives in patients who fail to respond. Therapeutic drug monitoring may assist. CF patients should also be assessed for drug interactions with their medication profile prior to commencement of itraconazole.[5]
- Itraconazole may prolong the QT interval and should be used with caution in combination with other drugs that may also prolong the QT interval due to the risk of serious cardiovascular events.[2, 6]

FORMULATIONS

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

- 50 mg capsules (Lozanoc®)
- 10 mg/mL oral solution – only available via the Special Access Scheme

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Itraconazole is not routinely used in neonates, contact Infectious Disease consultants for advice.

Dose equivalence: One 50 mg Lozanoc® (suprabioavailable itraconazole) capsule is equivalent to one 100 mg conventional itraconazole (Itracap® or Itranox®) capsule.[3]

Lozanoc® capsules:

Note: Doses below refer to the Lozanoc® brand of itraconazole only

Treatment doses:

Children >4 weeks to <12 years old:

- **Usual dose:** 1.25 - 2 mg/kg/dose (to a maximum initial dose of 100 mg) given twice daily. Dose should be adjusted based on therapeutic drug monitoring.(1)
- The dose may be increased to 5 mg/kg/dose (to a maximum initial dose of 100 mg) given twice daily for severe infections. The maximum daily dose may be increased based on therapeutic drug monitoring in discussion with Infectious Diseases.(1)
- The dose should be rounded to the nearest 50 mg to facilitate administration.(1)

Children ≥ 12 years old:

- **Usual dose:** 50 mg to 100 mg once daily. Dose may be increased to 100 mg twice daily in severe infections.(1)

Prophylaxis doses:

Children ≥ 2 years old:

- 2.5 mg/kg/dose given once daily (to a maximum initial dose of 200 mg daily). Dose should be adjusted based on therapeutic drug monitoring.(1)

Oral liquid:

Treatment doses:

Children >4 weeks to <12 years old:

Note: Bioavailability of the oral liquid in the fasting state is 60% higher than from the conventional itraconazole capsule taken with food.(1)

- **Usual dose:** 1.5 – 2.5 mg/kg/dose (to a maximum initial dose of 200 mg) given twice daily. Dose should be adjusted based on therapeutic drug monitoring. (1, 3)
- The dose may be increased to 5 mg/kg/dose (to a maximum initial dose of 100 mg) given twice daily for severe infections. The maximum daily dose may be increased based on therapeutic drug monitoring in discussion with Infectious Diseases. (1)

Prophylaxis doses:

Children ≥ 2 years old:

- 2.5 mg/kg/dose (to a maximum initial dose of 200 mg) given twice daily. Dose should be adjusted based on therapeutic drug monitoring.(1)

Dosing in Overweight and Obese Children: No information currently available.

Renal impairment:

- Dosage reduction is generally not required in cases of significant renal impairment. However, there is a possibility of a reduced oral bioavailability.(6)
- Large variations in plasma concentrations have been observed in adult patients with uraemia or receiving peritoneal dialysis or haemodialysis. Therapeutic drug monitoring should be utilised.(5)

Hepatic impairment:

- Itraconazole should be used with caution in patients with hepatic impairment.[7]
- Dose reduction and close monitoring of liver function and therapeutic drug monitoring is required. [5, 6]

ADMINISTRATION

- **Lozanoc® 50 mg capsules:** May be taken with or without food.[1]
- **Itraconazole oral solution:** The oral solution should be administered on an empty stomach approximately 1 hour before food or 2 hours after food. Absorption may be reduced if administered via a feeding tube.[1]

MONITORING

- Therapeutic drug monitoring is required due to the large variation in plasma concentrations with both formulations. Due to the long half-life of itraconazole, trough levels should be taken at least 7 days:
    - After starting treatment,
    - After any dose change or
    - After any change in formulation.
- It should be noted that steady state may not be reached until 11 to 14 days of therapy.[5, 8]
- Therapeutic drug monitoring is required for all patients receiving itraconazole for treatment of an invasive fungal infection and in children with potentially altered pharmacokinetics .[9]
- **Target trough levels:**
    - Prophylaxis: 0.5-4 mg/L
    - Treatment: 1-4 mg/L.[5, 8, 9]
    - Trough levels associated with toxicity are not well established, however levels less than 5 mg/L are recommended.[5]
- **Collection tube:**
    - **Paediatric:** Serum, no gel (RED) or Lithium heparin, No gel (DKGNLITH) [8]
    - **Minimum volume required:** 1 mL[8]
- Renal and hepatic function, complete blood picture and potassium levels should be monitored in patients taking itraconazole for 1 month or longer and in all patients with risk factors for hepatotoxicity regardless of duration of therapy.[3, 5, 6]
- Patients should be counselled to contact the prescriber if they experience any signs or peripheral neuropathy or symptoms suggestive of hepatitis including anorexia, nausea, vomiting, fatigue, abdominal pain, pale faeces, yellowing of the whites of the eyes or dark urine.[3]

ADVERSE EFFECTS

Common: dyspepsia, anorexia, fatigue, itch, dizziness, rash, headache, nausea, vomiting, abdominal pain, dyspnoea, diarrhoea, constipation, elevated lever enzymes, alopecia, pulmonary oedema, hypotension, skin reactions.[3, 7]

Infrequent: altered taste, hearing loss, insomnia, somnolence, gynaecomastia, impotence, flatulence [3, 7]

Rare: hypertension (with high dose), peripheral oedema, pulmonary oedema, heart failure, severe cutaneous adverse reactions (SCARs) , hypokalaemia (more common with high dose), reversible adrenal insufficiency (with high dose), thrombocytopenia and other blood dyscrasias, serious hepatotoxicity including hepatic failure, anaphylaxis, peripheral neuropathy, menstrual disorder, pancreatitis, urinary frequency, visual disturbances, tinnitus.[3, 7]

STORAGE

- All formulations of itraconazole should be stored below 25°C.[2]
- Oral solution: Discard 30 days after first opening.[10]

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 **itraconazole**. 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. Royal Australian College of General Practitioners, Pharmaceutical Society of Australia, Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists. AMH: Children's Dosing Companion. Adelaide: Australian Medicines Handbook Pty Ltd; 2022.
2. AusDI [Internet]. Health Communication Network Pty Ltd. 2025 [cited 2025 March 6th].
3. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2025 [cited 2025 6th March]. Available from: https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/.
4. Antibiotic Writing Group. Therapeutic Guidelines - Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2022. Available from: https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess.

5. Up To Date - Paediatric Drug information [Internet]. Lexicomp. 2025 [cited 2025 March 6th]. Available from: https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information.
6. Clinical Pharmacology powered by ClinicalKey [Internet]. Elsvier. 2025 [cited 2025 March 6th]. Available from: https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/.
7. Paediatric Formulary Committee. BNF for Children: 2025. London: BMJ Group Pharmaceutical Press; 2025.
8. PathWest. PathWest - test directory Perth2025 [cited 2025. Available from: https://pathwesttd.health.wa.gov.au/testdirectory/.
9. Chau MM, Daveson K, Alffenaar J-WC, Gwee A, Ho SA, Marriott DJE, et al. Consensus guidelines for optimising antifungal drug delivery and monitoring to avoid toxicity and improve outcomes in patients with haematological malignancy and haemopoietic stem cell transplant recipients, 2021. Internal Medicine Journal. 2021;51(S7):37-66.
10. Electronic Medicines Compendium (emc). Surrey: DataPharm Ltd; 2024.

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