



MONOGRAPH

Terbinafine Monograph - Paediatric

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| Scope (Staff): | Clinical Staff – Medical, Nursing, Pharmacy |
| Scope (Area): | Perth Children's Hospital (PCH) |
| Child Safe Organisation Statement of Commitment The Child and Adolescent Health Service (CAHS) commits to being a child safe organisation by meeting the National Child Safe Principles and National Child Safe Standards. This is a commitment to a strong culture supported by robust policies and procedures to ensure the safety and wellbeing of children at CAHS. | |

This document should be read in conjunction with this [DISCLAIMER](#)

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| DESCRIPTION | <ul style="list-style-type: none">Terbinafine is an antifungal agent that is fungicidal against dermatophytes and fungistatic against <i>Candida albicans</i>. It inhibits fungal ergosterol synthesis leading to disruption of the cell membrane and cell death.⁽¹⁻³⁾ |
| INDICATIONS AND RESTRICTIONS | <ul style="list-style-type: none">Terbinafine is indicated in the treatment of dermatophyte infections of the skin and nails.⁽¹⁻³⁾ <p>Oral: Unrestricted (green) antifungal</p> <ul style="list-style-type: none">This is not a restricted agent. Follow standard ChAMP guidelines where appropriate. |
| CONTRAINDICATIONS | <ul style="list-style-type: none">Terbinafine is contraindicated in patients with a hypersensitivity to terbinafine or any components of the formulation.^(3, 4)Oral terbinafine is contraindicated in patients with severe, chronic or active hepatic disease.⁽¹⁻⁴⁾ |
| PRECAUTIONS | <ul style="list-style-type: none">Terbinafine may exacerbate or precipitate psoriasis or lupus erythematosus.^(1, 5) |
| FORMULATIONS | <p>Available at PCH:</p> <ul style="list-style-type: none">250mg tablets1% (10mg/mg) Cream <p>Other preparations available:</p> <ul style="list-style-type: none">Multiple generic brands |
| DOSAGE | <ul style="list-style-type: none">The doses listed below fall within the standard range.Higher doses may be prescribed for certain situations in consultation with an infectious diseases or clinical microbiology consultant. |

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| | <p>Neonates and children <12 months old:</p> <p>Not routinely used in children under 12 months of age. Contact Infectious Diseases for advice.</p> <p>Children ≥12 months:</p> <p>Topical:</p> <p>Used for localised skin infections of the trunk, limbs, feet and groin. Apply to the affected area(s) once daily Treat for 1–4 weeks.⁽⁶⁾</p> <p>Oral:</p> <p>Tinea of the nails, palms, soles (or skin if topical treatment has failed) - treatment duration 2 to 6 weeks (6 weeks therapy is required for fingernails and 12 weeks therapy for toenails)⁽⁶⁾</p> <p>≥10 to <20kg: 62.5mg once daily ≥20 to <40kg: 125mg once daily ≥40kg: 250mg once daily⁽⁴⁻⁶⁾</p> <p>Tinea capitis – treatment duration 4 to 6 weeks.⁽⁶⁾</p> <p>10-25kg: 125mg once daily 25-35kg: 187.5mg once daily >35kg: 250mg once daily^(4, 6)</p> |
| DOSAGE ADJUSTMENT | <p>Dosage adjustment required in renal impairment:</p> <ul style="list-style-type: none"> Dosage adjustment for oral therapy may be required in cases of impaired renal function (with creatinine clearance of less than 50mL/min).^(1, 5) To calculate the estimated glomerular filtration rate (eGFR) use the following formula: $\text{eGFR (mL/min/1.73m}^2\text{)} = \frac{36.5 \times \text{height (in cm)}}{\text{Serum creatinine (micromol/L)}}$ <p>CrCL ≥50mL/minute: normal dose CrCL <50mL/minute: 50% of normal dose given once daily.⁽⁵⁾</p> <p>Dosage adjustment required in hepatic impairment:</p> <p>Oral terbinafine is contraindicated in patients with severe, chronic or active hepatic disease.^(1, 4)</p> |
| RECONSTITUTION | <ul style="list-style-type: none"> Not applicable |

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| ADMINISTRATION | <ul style="list-style-type: none"> Topical: clean and dry skin thoroughly before applying a thin layer to the affected area(s) and surrounding skin⁽⁶⁾ Oral: Terbinafine may be taken without regard to food and the tablet may be crushed. However if stomach upset occurs, taking the tablet with or after food may assist.^(2-4, 7) |
| MONITORING | <ul style="list-style-type: none"> For patients requiring treatment for more than 6 weeks, baseline liver function tests should be performed and monitored throughout treatment.^(1, 4, 5) |
| ADVERSE EFFECTS | <p>The following side effects apply to oral treatment:</p> <p>Common:</p> <ul style="list-style-type: none"> Nausea, vomiting, diarrhoea, abdominal pain, rash, itch, urticaria, transient elevation of liver enzymes, arthralgia, myalgia, headache.^(1, 5) <p>Rare:</p> <ul style="list-style-type: none"> Taste disturbance, hepatitis, hepatic failure, neutropenia, agranulocytosis, thrombocytopaenia, pancytopenia, anaemia, Stevens-Johnson Syndrome, toxic epidermal necrolysis, psoriasiform lesions, photosensitivity, lupus erythematosus, alopecia, anaphylaxis, dizziness, depression, paraesthesia.^(1, 2, 5) <p>Side effects from topical treatment are infrequent but may include: redness, itch, stinging.</p> |
| COMPATIBLE FLUIDS | <ul style="list-style-type: none"> Not applicable |
| STORAGE | <ul style="list-style-type: none"> Store cream below 25° Store tablets below 25°C and protect from light.⁽²⁾ |
| INTERACTIONS | <p>Oral terbinafine may interact with other medications; please consult PCH approved references (e.g. <u>Clinical Pharmacology</u>), your ward pharmacist or Pharmacy on extension 63546 for more information.</p> <ul style="list-style-type: none"> Terbinafine is a strong inhibitor of CYP2D6, potentially increasing the concentrations of adverse effects of medications metabolised by this enzyme. It has a very long half-life and its potential to interact may last for months after stopping treatment.⁽¹⁾ Rifampicin increases the metabolism of terbinafine, decreasing its concentration and reducing its antifungal effect; if using rifampicin long term consider doubling the terbinafine dose and monitoring clinical response; it may be possible to delay terbinafine treatment until after rifampicin course.⁽¹⁾ Terbinafine may increase exposure to Selective Serotonin Reuptake inhibitors (SSRI's) such as citalopram, escitalopram, fluoxetine and fluvoxamine by reducing their metabolism. |

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| | <p>Monitor for increased SSRI adverse effects.⁽⁵⁾</p> <ul style="list-style-type: none"> Terbinafine may increase exposure to Tricyclic Antidepressants such as imipramine and amitriptyline by reducing their metabolism. Monitor for increased adverse effects.⁽⁵⁾ |
| COMMENTS | <ul style="list-style-type: none"> Patients should be instructed to inform the treating team if they develop dark urine, pale faeces, yellowing of the whites of the eyes or skin, fever, mouth ulcers or sore throat, unusual bruising or start feeling unusually tired or nauseous which may indicate hepatotoxicity.⁽¹⁾ |
| MANUFACTURER SAFETY DATA SHEET (SDS) | To access to the Manufacturer SDS for this product, use the following link to ChemAlert . |

Please note: The information contained in this guideline is to assist with the preparation and administration of **terbinafine**. 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 and related external legislation, policies, and guidelines

- Rossi S, editor. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2020.
- MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2020. p. 1v. (various pagings).
- Clinical Pharmacology [Internet]. Elsevier BV. 2021 [cited 14/01/2021]. Available from: <http://www.clinicalpharmacology-ip.com.pklibresources.health.wa.gov.au/default.aspx>.
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- Paediatric Formulary Committee. BNF for Children: 2020. London: BMJ Group Pharmaceutical Press; 2021.
- 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; 2018.
- Burridge N, Deidun D (editors). Australian Don't Rush to Crush Handbook. Therapeutic options for people unable to swallow solid oral medicines. 3rd edition ed. Collingwood: The Society of Hospital Pharmacists of Australia; 2018.

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