



## MONOGRAPH

### Terbinafine 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

[Dosage/Dosage  
Adjustments](#)

[Administration](#)

[Compatibility](#)

[Monitoring](#)

#### DRUG CLASS

Antifungal (allylamine class).<sup>(1, 2)</sup>

#### INDICATIONS AND RESTRICTIONS

Terbinafine is indicated in the treatment of onychomycosis and tinea due to dermatophytes, including tinea capitis, tinea corporis, tinea cruris and tinea pedis.<sup>(2-5)</sup>

##### Oral: Unrestricted (green) antifungal

This is not a restricted agent. Follow standard ChAMP guidelines where appropriate.

#### CONTRAINDICATIONS

- Hypersensitivity to terbinafine or any component of the formulation.<sup>(2, 4-6)</sup>
- Oral terbinafine is contraindicated in patients with chronic or active hepatic disease.<sup>(3-6)</sup>

#### PRECAUTIONS

- Terbinafine may worsen or precipitate psoriasis.<sup>(2, 3, 7)</sup>
- Terbinafine may exacerbate or precipitate systemic or cutaneous lupus erythematosus.<sup>(2, 3, 5, 7)</sup>

## FORMULATIONS

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

- 250 mg tablets
- 1% (10 mg/mg) cream

Imprest location: [Formulary One](#)

## DOSAGE & DOSAGE ADJUSTMENTS

### Neonates and children <12 months old or weighing less than 10kg:

- Not routinely used in children under 12 months of age or weighing less than 10 kg. Contact Infectious Diseases for advice.

### Children ≥12 months:

| Topical  |  |  |
|--|--|--|
| Indication                                       | Dose   | Duration   |
| Local infections of trunk, limbs, feet and groin | Apply to the affected area(s) once or twice daily <sup>(8)</sup> | Tinea pedis (athletes foot): 2-6 weeks<br>Tinea corporis (body ringworm): 4 weeks<br>Tinea curis (tinea of the groin): 2-4 weeks <sup>(6)</sup>                        |
| Oral   |  |  |
| Onychomycosis <sup>(1, 5, 7-9)</sup>             | ≥ 10 kg to < 20 kg: 62.5mg once daily                            | Until clinical clearance (review at 3 months of treatment) <sup>(9)</sup><br>- New nail will take 9 to 12 months to grow <sup>(9)</sup>                                |
|  | ≥ 20 kg to < 40 kg: 125mg once daily                             |  |
|  | ≥ 40 kg: 250mg once daily.                                       |  |
| Tinea <sup>(1, 8, 9)</sup>                       | ≥ 10 kg to < 20 kg: 62.5mg once daily                            | Skin - 2 weeks (longer treatment may be required on hyperkeratotic or hairy areas of the body). <sup>(9)</sup><br>Tinea capitis – 4 to 6 weeks <sup>(3, 5, 8, 9)</sup> |
|  | ≥ 20 kg to < 40 kg: 125mg once daily                             |  |
|  | ≥ 40 kg: 250mg once daily.                                       |  |

**Dosing in Overweight and Obese Children:**

There is minimal information regarding the dosing of terbinafine in obese or overweight children. Based on the pharmacokinetic properties, dosing based on total body weight is appropriate.<sup>(10)</sup>

**Renal impairment:**

- [eGFR calculator](#)
- There is minimal paediatric data regarding dose adjustment in renal impairment. Adult studies give the following dose adjustments.<sup>(5)</sup>

| eGFR                                      | Dose adjustment               |
|---|-------------------------------|
| ≥ 50 mL/minute/1.73m <sup>2</sup>         | Normal dosing                 |
| ≥ 20 to < 50 mL/minute/1.73m <sup>2</sup> | Give 50% of the usual dose    |
| < 20 mL/minute/1.73m <sup>2</sup>         | Consider an alternative agent |

**Hepatic impairment:**

- Oral terbinafine is contraindicated in patients with severe, chronic or active hepatic disease.<sup>(3-6)</sup>
- There are not dose adjustments recommended in the manufacturers information. Patients with hepatic cirrhosis have a reduced clearance of terbinafine and therefore increased exposure with standard dosing.<sup>(2, 5, 7)</sup>

**ADMINISTRATION**

- **Topical:** Clean and dry skin thoroughly before applying a thin layer to the affected area(s) and surrounding skin.<sup>(4, 9)</sup>
- **Oral:** Terbinafine may be taken without regard to food and the tablet may be crushed and mixed with water or soft food.<sup>(4, 11)</sup>

**MONITORING**

- Baseline liver function tests should be performed and monitored every 4 to 6 weeks throughout treatment and treatment ceased if any abnormalities occur.<sup>(2, 3, 6, 7)</sup>
- In known or suspected immunosuppressed patients, full blood picture should be assessed if the course is longer than 6 weeks.<sup>(4)</sup>
- 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.<sup>(3, 6)</sup>

## ADVERSE EFFECTS

### Oral therapy:

**Common:** Nausea, vomiting, reduced appetite, diarrhoea, abdominal pain, gastritis, rash, itch, urticaria, transient elevation of liver enzymes, arthralgia, myalgia, headache.<sup>(2, 3, 7)</sup>

**Infrequent:** altered taste<sup>(3, 7)</sup>

**Rare:** hepatitis, hepatic failure, neutropenia, agranulocystosis, thrombocytopaenia, pancytopenia, anaemia, severe cutaneous adverse reactions (SCARs), Stevens-Johnson Syndrome, toxic epidermal necrolysis, psoriasiform lesions, photosensitivity, lupus erythematosus (cutaneous or systemic), alopecia, anaphylaxis, dizziness, depression, paraesthesia.<sup>(3, 7)</sup>

### Topical therapy:

Side effects from topical treatment are infrequent but may include: redness, itch, stinging.<sup>(2)</sup>

## STORAGE

- Store tablets and topical cream below 25°C and protect from light.<sup>(2, 6)</sup>

## 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 **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




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. 2024 [cited 2024 February 21st].
3. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2023 [cited 2024 10th January]. Available from: <https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/>.
4. Clinical Pharmacology powered by ClinicalKey [Internet]. Elsevier. 2024 [cited 2024 February 21st]. Available from: <https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/>.
5. Up To Date - Paediatric Drug information [Internet]. Lexicomp. 2023 [cited 2024 February 21st]. Available from: <https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information>.
6. Electronic Medicines Compendium (emc). Surrey: DataPharm Ltd; 2024.

7. Paediatric Formulary Committee. BNF for Children: 2023. London: BMJ Group Pharmaceutical Press; 2023.
8. The Australian Healthy Skin Consortium. National Healthy Skin guidelines: for the Diagnosis, Treatment and Prevention of Skin Infections for Aboriginal and Torres Strait Islander Children and Communities in Australia. 2023;2nd Edition.
9. 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>.
10. Ross EL, Heizer J, Mixon MA, Jorgensen J, Valdez CA, Czaja AS, Reiter PD. Development of recommendations for dosing of commonly prescribed medications in critically ill obese children. American Journal of Health-System Pharmacy. 2015;72(7):542-56.
11. Symons K, Emer J (editors). Australian Don't Rush to Crush Handbook. 4th edition ed. Collingwood: The Society of Hospital Pharmacists of Australia; 2021.

### Useful resources (including related forms)

[National Healthy Skin guidelines: for the Diagnosis, Treatment and Prevention of Skin Infections for Aboriginal and Torres Strait Islander Children and Communities in Australia. 2023;2nd Edition.](#)

This document can be made available in alternative formats on request.

|   |   |                    |               |
|---|---|--------------------|---------------|
| File Path:  | <a href="#">W:\Safety &amp; Quality\CAHS\CLOVERS MEDICAL Pharmacy\Procedures Protocols and Guidelines\ChAMP\Word</a>  |                    |               |
| Document Owner:                                   | Head of Department – Infectious Diseases  |                    |               |
| Reviewer / Team:                                  | Children's Antimicrobial Management Program Pharmacist  |                    |               |
| Date First Issued:                                | February 2021   | Last Reviewed:     | February 2024 |
| Amendment Dates:                                  | February 2024   | Next Review Date:  | March 2027    |
| Approved by:                                      | Drug and Therapeutics Committee   | Date:              | March 2024    |
| Endorsed by:                                      | Chair, Drug and Therapeutics Committee  | Date:              | March 2024    |
| Aboriginal Impact Statement and Declaration (ISD) |   | Date ISD approved: | August 2023   |
| Standards Applicable:                             | NSQHS Standards:   <br>NSMHS: N/A<br>Child Safe Standards: N/A |                    |               |

Printed or personally saved electronic copies of this document are considered uncontrolled



Healthy kids, healthy communities

Compassion

Excellence

Collaboration

Accountability

Equity

Respect

Neonatology | Community Health | Mental Health | Perth Children's Hospital