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).[1, 2]

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.[2-5]

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.[2, 4-6]
- Oral terbinafine is contraindicated in patients with chronic or active hepatic disease.[3-6]

PRECAUTIONS

- Terbinafine may worsen or precipitate psoriasis.[2, 3, 7]
- Terbinafine may exacerbate or precipitate systemic or cutaneous lupus erythematosus.[2, 3, 5, 7]

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[8]	Tinea pedis (athletes foot): 2-6 weeks Tinea corporis (body ringworm): 4 weeks Tinea curis (tinea of the groin): 2-4 weeks[6]
Oral		
Onychomycosis[1, 5, 7-9]	≥ 10 kg to < 20 kg: 62.5mg once daily	Until clinical clearance (review at 3 months of treatment)[9] - New nail will take 9 to 12 months to grow[9]
	≥ 20 kg to < 40 kg: 125mg once daily	
	≥ 40 kg: 250mg once daily.	
Tinea [1, 8, 9]	≥ 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).[9] Tinea capitis – 4 to 6 weeks[3, 5, 8, 9]
	≥ 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.[10]

Renal impairment:

- eGFR calculator
- There is minimal paediatric data regarding dose adjustment in renal impairment. Adult studies give the following dose adjustments.[5]

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

Hepatic impairment:

- Oral terbinafine is contraindicated in patients with severe, chronic or active hepatic disease.[3-6]
- 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.[2, 5, 7]

ADMINISTRATION

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

MONITORING

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

ADVERSE EFFECTS

Oral therapy:

Common: Nausea, vomiting, reduced appetite, diarrhoea, abdominal pain, gastritis, rash, itch, urticaria, transient elevation of liver enzymes, arthralgia, myalgia, headache.[2, 3, 7]

Infrequent: altered taste[3, 7]

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.[3, 7]

Topical therapy:

Side effects from topical treatment are infrequent but may include: redness, itch, stinging.[2]

STORAGE

- Store tablets and topical cream below 25°C and protect from light.[2, 6]

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

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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 Handboook. 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.

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