MONOGRAPH

Griseofulvin Monograph - Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing,
Scope (Area):	All Clinical Areas – Perth Children's Hospital

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				
<u>Dosage/Dosage</u> <u>Adjustments</u>	<u>Administration</u>	Compatibility	Monitoring	

DRUG CLASS

Antifungal⁽¹⁾

INDICATIONS AND RESTRICTIONS

Griseofulvin is used in the treatment of dermatophyte infections of the skin that:

- Are widespread and/or hyperkeratotic
- Involve sites where topical treatment is not recommended (e.g. infection involving the scalp, palms or soles) or
- Have not responded to topical therapy. (2, 3)

An accurate mycological diagnosis is desirable prior to commencing griseofulvin treatment as its activity is restricted to dermatophyte infections. Griseofulvin has no activity against yeasts such as *Candida* species or *Malassezia furfur*. (1, 4)

Oral: Unrestricted (green) antifungal

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

CONTRAINDICATIONS

- Hypersensitivity to griseofulvin or any component of the formulation.
- Griseofulvin is category D and is contraindicated in pregnancy and women intending to become pregnant within one month of cessation of griseofulvin treatment. (2, 5) The manufacturer advises men not to father children during and for 6 months after treatment as griseofulvin may affect sperm. (2)

- Griseofulvin is contraindicated in patients with Lupus erythematosus. (1, 5-7)
- Griseofulvin is contraindicated in severe liver disease as it may cause liver function to worsen. (5)
- Griseofulvin is contraindicated in patients with acute porphyrias due to the risk of inducing a porphyric crisis.⁽⁵⁻⁷⁾

PRECAUTIONS

- Patients should avoid exposure to sunlight due to the risk of photosensitivity reactions.
 Patients should be instructed to wear protective clothing, a hat, sunglasses and sunscreen (physical sunscreen is preferred to chemical sunscreen) while taking griseofulvin. (1, 5)
- Griseofulvin reduces the efficacy of the oral contraceptive pill, sexually active adolescent females should use effective non-hormonal contraception whilst taking griseofulvin and for at least 4 weeks after ceasing therapy.⁽¹⁾

FORMULATIONS

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

125mg and 500mg oral tablets

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Not routinely used in neonates (less than 30 days of age), contact Infectious Diseases or Clinical Microbiology for advice.

Children:

1 month to 12 years: 10-20mg/kg (to a maximum of 1gram) once daily. If using the higher dose, reduce dose when clinical improvement occurs. $^{(2, 4, 6)}$

>12 years to 18 years: 500mg daily. Up to 1gram daily can be used for severe infections; reduce dose once response occurs. (2, 4, 6)

Use the higher dose in patients being treated for tinea capitis caused by *Trichophyton tonsurans*, or alternatively, use <u>terbinafine</u>. (6)

Duration of therapy is dependent on the site of the infection.

- Tinea capitis: 4 to 6 weeks
- Tinea corporis: 2 to 4 weeks
- Tinea unguium (onychomycosis): at least 4 months for fingernails and at least 6 months for toes nails.⁽⁵⁾

Renal impairment:

• Dosage reduction is generally not required in cases of significant renal impairment. Contact Pharmacy for advice. (5, 7)

Hepatic impairment:

 Although no specific dose adjustments are required, griseofulvin is contraindicated in severe liver disease as it undergoes hepatic metabolism and may worsen liver function. (5-7)

ADMINISTRATION

• Griseofulvin should be administered with a high fat meal (for example peanut butter or ice-cream) or milk to increase absorption and to avoid stomach upset. (1, 5, 7)

COMPATIBILITY

Not applicable

MONITORING

 Renal, hepatic and haematological function should be monitored periodically if treatment course is 8 weeks or longer.^(1, 2, 5, 7)

ADVERSE EFFECTS

Common: headache, nausea, diarrhoea, anorexia. (1, 6)

Infrequent: photosensitivity, urticaria, rash, blurred vision, confusion, fatigue, dizziness, taste disturbance, insomnia, irritability, dyspepsia. (1,6)

Rare: toxic epidermal necrolysis, precipitation or exacerbation of lupus erythematosus, vomiting, abdominal pain, severe diarrhoea, menstrual irregularities, leucopenia, neutropenia, hypersensitivity (e.g. serum sickness like reaction), hepatotoxicity, .^(1, 6)

STORAGE

Store tablets below 30°C⁽²⁾

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.

Related CAHS internal policies, procedures and guidelines

Antimicrobial Stewardship Policy

ChAMP Empiric Guidelines and Monographs

KEMH Neonatal Medication Protocols

^{**}Please note: The information contained in this guideline is to assist with the preparation and administration of **griseofulvin**. Any variations to the doses recommended should be clarified with the prescriber prior to administration**

References

- 1. Rossi S, editor. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2021.
- 2. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2021. p. 1v. (various pagings).
- 3. Antibiotic Writing Group. eTG complete. West Melbourne: Therapeutic Guidelines Ltd; 2020. Available from: https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess.
- 4. 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; 2020.
- 5. Clinical Pharmacology [Internet]. Elsvier BV. 2021 [cited 14/01/2021]. Available from: http://www.clinicalpharmacology-ip.com.pklibresources.health.wa.gov.au/default.aspx.
- 6. Paediatric Formulary Committee. BNF for Children: 2020. London: BMJ Group Pharmaceutical Press; 2021.
- 7. Taketomo CK, Hodding JH, Kraus DM. Pediatric and Neonatal dosage handbook with international trade names index. 26th edition ed. Ohio: Lexi-comp; 2019-2020.

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