MONOGRAPH

Nitrofurantoin 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

DRUG CLASS

Nitrofuran antibacterial.[1]

INDICATIONS AND RESTRICTIONS

- Nitrofurantoin is used in the treatment and prophylaxis of lower urinary tract infections resistant to other first line agents.[2-4]
- Nitrofurantoin is not suitable for use in the treatment of complicated urinary tract infections or pyelonephritis due to inadequate systemic concentrations.[2, 4, 5]

Oral: Unrestricted (green) antibiotic

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

CONTRAINDICATIONS

- Hypersensitivity to, or a history of cholestatic jaundice or hepatic dysfunction associated with nitrofurantoin or any component of the formulation.[1, 3-5]
- Nitrofurantoin is contraindicated in patients with oliguria or anuria due to the increased risk of toxicity.[1, 3-5]
- Nitrofurantoin is contraindicated in neonates due to the risk of haemolytic anaemia as the red bloods cells lack sufficient quantities of reduced glutathione.[3, 4]

PRECAUTIONS

- Nitrofurantoin is generally contraindicated if eGFR <45 mL/minute/1.73 m^2. However, it may be used for 3 – 7 days for selected patients whose eGFR is 30 – 45 mL/minute/1.73 m^2 and who have a multidrug-resistant UTI.[6]
- Nitrofurantoin should be avoided in patients with glucose-6-phosphate dehydrogenase deficiency (G6PD), enolase or glutathione peroxidase deficiency due to the risk of haemolytic anaemia.[1, 2, 4-6]
- Nitrofurantoin may discolour urine to a dark yellow or brown colour.[2, 6]

FORMULATIONS

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

- 50 mg capsules
- 10 mg/mL suspension (Auspman®)

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates:

- Nitrofurantoin is contraindicated in neonates due to the risk of haemolytic anaemia. Contact an infectious diseases or clinical microbiology consultant for advice on alternative options.[1, 5]

Oral: Children (≥ 4 weeks)

Uncomplicated lower urinary tract infection:

- Treatment: 0.75 mg to 1.75 mg/kg/dose (to a maximum of 100 mg) given four times daily.[1, 2, 4-6] In children who can swallow capsules, consider the following dose bands:

  Weight >29 kg to < 50 kg: 50 mg given four times daily

  Weight ≥ 50 kg: 100 mg four times daily.[7]

- Prophylaxis: 1 - 2 mg/kg/dose (to a maximum of 100 mg) given once daily at bedtime.[1, 2, 4-6] In children who can swallow capsules, consider the following dose bands:

  Weight >25 kg to < 50 kg: 50 mg once daily

  Weight ≥ 50 kg: 100 mg once daily.

Dosing in Overweight and Obese Children: There is minimal information available regarding dosing of nitrofurantoin in overweight or obese patients. Based on pharmacokinetic parameters, consider dosing based on adjusted body weight using a co-factor of 0.35.[8, 9]

Renal impairment:

eGFR calculator

- eGFR < 45 mL/minute/1.73m^2: avoid use if alternative agents are available.[6, 10]
- eGFR ≥ 30 to <45 mL/minute/1.73m^2: Use with caution for 3 to 7 days in the treatment of an uncomplicated urinary tract infection due to multi-drug resistant bacteria when benefits are likely to outweigh risks.[6, 10]
- eGFR < 30 mL/minute/1.73m^2: contraindicated. Urinary concentrations may be inadequate and higher plasma concentrations may increase the risk of adverse effects.[6, 10]

Hepatic impairment:

- No dosage adjustments are required in hepatic impairment, but nitrofurantoin should be used with caution as use is associated with hepatotoxicity (including hepatitis, cholestatic jaundice, chronic active hepatitis and hepatic necrosis).[3, 5]

ADMINISTRATION

- Oral doses should be given with food or milk to reduce nausea and improve absorption.[1, 2, 4, 5]

MONITORING

During long term prophylaxis monitor:

- Pulmonary function; if respiratory symptoms occur perform a chest X-ray and consider pulmonary function tests. X-ray changes (pulmonary infiltration with consolidation or pleural effusion) and electrocardiogram (ECG) changes (which may be associated with pulmonary reactions) may occur on long term prophylaxis. [1, 2, 4, 6, 7]
- Renal function as peripheral neuropathy is more likely with impaired renal function.[1, 2, 4, 7]
- For development of paraesthesia as early cessation can prevent severe neuropathy.[2]
- Liver function tests monthly for the first three months, then three-monthly thereafter whilst on extended prophylactic therapy.[1, 2, 4, 6, 7]

ADVERSE EFFECTS

Common: nausea and vomiting, anorexia, diarrhoea, abdominal pain, allergic skin reactions, headache.[2]

Infrequent: drowsiness, vertigo, dizziness[2]

Rare: pulmonary toxicity (reversible allergic pneumonitis, often within the first week or chronic – interstitial pulmonary fibrosis generally after approximately 6 months), peripheral polyneuropathy (usually presents as peripheral paraesthesia and sensory loss in the lower limbs, risk is increased in renal impairment), hepatotoxicity, skin reactions (Stevens-Johnson syndrome, exfoliative dermatitis), lupus-like syndrome, anaphylaxis, drug fever, eosinophilia and arthralgia.[2]

STORAGE

- Capsules: store below 25˚C[3]
- Suspension: Store below 25˚C

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 **nitrofurantoin**. 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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