

Children's Antimicrobial Management Program (ChAMP)

### 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**

	QUICKLINKS					
Administration	Compatibility	Monitoring				
	<u>Administration</u>	Administration Compatibility				

Nitrofuran antibacterial.<sup>(1)</sup>

#### INDICATIONS AND RESTRICTIONS

- Nitrofurantoin is used in the treatment and prophylaxis of lower urinary tract infections resistant to other first line agents.<sup>(2)</sup>
- Nitrofurantoin is not suitable for use in the treatment of complicated urinary tract infections or pyelonephritis due to inadequate systemic concentrations.<sup>(2)</sup>

#### 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.<sup>(1, 2)</sup>
- Nitrofurantoin is contraindicated in patients with oliguria or anuria due to the increased risk of toxicity.<sup>(1)</sup>
- Nitrofurantoin is contraindicated in neonates due to the risk of haemolytic anaemia as the red bloods cells lack sufficient quantities of reduced glutathione.<sup>(1, 3)</sup>

#### PRECAUTIONS

- Nitrofurantoin is generally contraindicated if eGFR <45 mL/minute/1.73 m<sup>2</sup>. However, it may be used for 3–7 days for selected patients whose eGFR is 30–45 mL/minute/1.73 m<sup>2</sup> and who have a multidrug-resistant UTI.<sup>(2, 4)</sup>
- 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.<sup>(1, 2)</sup>
- Nitrofurantoin may discolour urine to a dark yellow or brown colour.<sup>(2, 4)</sup>

#### FORMULATIONS

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

- 50mg capsules
- 100mg capsules
- 10mg/mL suspension (Auspman<sup>®</sup>)

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.<sup>(1)</sup>

#### Oral (≥4 weeks) - Uncomplicated lower urinary tract infection:

- Treatment: 0.75mg to 1.75mg/kg/dose (to a maximum of 100mg) given four times daily.<sup>(2, 4, 5)</sup>
- Prophylaxis: 1-2mg/kg/dose (to a maximum of 100mg) given once daily at bedtime.<sup>(2, 4, 5)</sup>

Antibiotic urinary prophylaxis is not routinely recommended for children following their first episode of a urinary tract infection (UTI). It may be considered for children with severe or recurrent UTIs or with vesicoureteric reflux grades III to V.<sup>(6)</sup>

#### **Renal impairment:**

#### eGFR calculator

- eGFR <45mL/minute: avoid use if alternative agents are available.<sup>(4)</sup>
- eGFR ≥30 to <45mL/minute: Use with caution for 3 to 7 days in the treatment of an uncomplicated urinary tract infection due to multi-drug resistant bacteria.<sup>(1, 4)</sup>
- eGFR <30mL/minute: contraindicated. Urinary concentrations may be inadequate and higher plasma concentrations may increase the risk of adverse effects.<sup>(2, 4)</sup>

#### Hepatic impairment:

 No dosage adjustments are required in hepatic impairment, but nitrofurantoin should be used with caution as use is associated with hepatotoxicity.<sup>(1, 3, 7)</sup>

#### ADMINISTRATION

• Oral doses should be given with food or milk to reduce nausea and improve absorption.<sup>(1, 2, 7)</sup>

#### MONITORING

During long term treatment 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 treatment. <sup>(1, 2, 4, 7)</sup>
- Renal function as peripheral neuropathy is more likely with impaired renal function.<sup>(1, 2)</sup>
- For development of paraesthesia as early cessation can prevent severe neuropathy.<sup>(2)</sup>
- Liver function tests monthly for the first three months, then three-monthly thereafter whilst on extended prophylactic therapy.<sup>(1, 2, 4)</sup>

#### **ADVERSE EFFECTS**

**Common:** nausea and vomiting, anorexia, diarrhoea, abdominal pain, allergic skin reactions, headache.<sup>(2)</sup>

Infrequent: drowsiness, vertigo, dizziness<sup>(2)</sup>

**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), hepatotoxicity, skin reactions (Stevens-Johnson syndrome, exfoliative dermatitis), lupus-like syndrome, anaphylaxis, drug fever, eosinophilia and arthralgia.<sup>(2)</sup>

#### STORAGE

- Capsules: store below 30°C<sup>(8)</sup>
- Suspension: Store below 25°C

#### **INTERACTIONS**

This medication may interact with other medications; consult PCH approved references (e.g. <u>Clinical Pharmacology</u>), 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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