**MONOGRAPH**

**Sodium Fusidate Monograph - Paediatric**

<table>
<thead>
<tr>
<th>Scope (Staff):</th>
<th>Clinical Staff – Medical, Nursing, Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope (Area):</td>
<td>Perth Children’s Hospital (PCH)</td>
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</tbody>
</table>

This document should be read in conjunction with this [DISCLAIMER](#).

**DESCRIPTION**

- Sodium fusidate is a narrow spectrum antibacterial which inhibits bacterial protein synthesis by preventing translocation of peptide subunits on the bacterial ribosome.\(^1\,^2\)
- Sodium fusidate is indicated as part of combination therapy in the treatment of serious Staphylococcus aureus infections – usually Methicillin Resistant Staphylococcus aureus (MRSA).\(^1\)
- Resistance develops rapidly and sodium fusidate must be used in combination with rifampicin to reduce the risk of resistance developing.\(^1\,^2\)

**INDICATIONS AND RESTRICTIONS**

Oral and topical: Red (restricted) antibiotic

- ChAMP approval is required prior to prescription.

**CONTRAINDICATIONS**

- Hypersensitivity to fusidic acid, its salts or any excipient in the formulation.\(^2\)
- Sodium fusidate must not be co-administered with a statin (HMG-CoA reductase inhibitor) drug – due to the increased risk of rhabdomyolysis. In cases where sodium fusidate is essential – the statin should be discontinued throughout treatment and for 7 days after treatment once sodium fusidate has ceased.\(^1\,^2\)

**PRECAUTIONS**

- Resistance to sodium fusidate develops rapidly, it must only be used in combination with other agents.\(^1\,^2\)

**FORMULATIONS**

Available at PCH:

- 250mg tablet - containing sodium fusidate (Fucidin®).
- 250mg/5mL suspension - containing fusidic acid (Fucidin®).
- Special Access Scheme (SAS) restrictions apply for the oral suspension.

Other formulations available:

- Sodium fusidate injection is not marketed in Australia but
Sodium Fusidate Monograph - Paediatric

<table>
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<tr>
<th>DOSAGE</th>
<th>may be available through the Special Access Scheme.</th>
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| • The doses listed below fall within the standard range.  
• Higher doses may be prescribed in certain situations in consultation with an Infectious Diseases or Clinical Microbiology consultant.  

**Sodium fusidate should always be used as part of a multidrug regimen.**  

250mg of fusidic acid (suspension) is therapeutically equivalent to 175mg sodium fusidate (tablet) due to incomplete absorption of oral fusidic acid.\(^{(3)}\)

**Neonates (<1 month of age):**  
Please refer to **Neonatal Medication Protocols**

**Oral doses of sodium fusidate (tablets):**  
• MRSA osteomyelitis and recurrent staphylococcal skin infection: 12mg/kg (to a maximum of 500mg) 8 hourly.\(^{(4)}\)

**Other infections:**  
• Children 5 to 12 years: 250mg three times a day.  
• Children >12 years: 500mg three times a day.\(^{(3)}\)

**Oral doses of fusidic acid (liquid):**  
• Children 1 month to 18 years: 15mg/kg (to a maximum of 750mg) every 8 hours. \(^{(3)}\)

**Topical**  
• Topical sodium fusidate should not be used as it promotes resistance, in most cases mupirocin ointment is a suitable alternative. \(^{(3, 4)}\)

| DOSAGE ADJUSTMENT | • No dosage adjustment required in renal impairment.\(^{(4, 5)}\)  
• Use with caution in patients with hepatic impairment as dose reduction may be required.\(^{(2, 5)}\) |
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<tr>
<td>RECONSTITUTION</td>
<td>Not applicable.</td>
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<tr>
<td>ADMINISTRATION</td>
<td>• <strong>Oral:</strong> Tablets and suspension are best absorbed on an empty stomach (1 hour before or 2 hours after food.) If stomach upset occurs, it may be taken after food. The tablets should be swallowed whole.(^{(1, 2)})</td>
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<td>MONITORING</td>
<td>• Hepatic function tests should be conducted regularly in patients on extended treatment, when high doses are used or in cases of pre-existing hepatic impairment.(^{(2, 6)})</td>
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<td>ADVERSE EFFECTS</td>
<td>• <strong>Common:</strong> nausea, vomiting, abdominal pain, dyspepsia, epigastric discomfort, diarrhoea, drowsiness, lethargy,</td>
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</table>
### Sodium Fusidate Monograph - Paediatric

| dizziness | Rare: anorexia, headache, malaise, rash, pruritus, thrombophlebitis, cholestasis, hepatorenal syndrome, reversible jaundice, raised serum aminotransferases, acute renal failure (usually in association with jaundice), blood disorders (leukopenia, thrombocytopenia). |

### COMPATIBLE FLUIDS
- Not applicable.

### STORAGE
- **Tablets:** store below 30 degrees Celsius. \(^{(2)}\)
- **Suspension:** store below 30 degrees Celsius. Protect from light and moisture. \(^{(2)}\)

### INTERACTIONS
**Sodium fusidate has a number of drug interactions; please consult PCH approved references (such as Clinical Pharmacology), your ward pharmacist or Pharmacy for more information.**

- Concurrent administration with statins increases the risk of myopathy including rhabdomyolysis.
- If treatment with sodium fusidate is necessary statin treatment should be discontinued for the duration of sodium fusidate treatment and for 7 days after ceasing. \(^{(1, 2, 6)}\)
- Concurrent administration with oral anticoagulants such as warfarin or those with similar action may increase the plasma concentration of the anticoagulant agent.
- Anticoagulant dosage adjustment, monitoring coagulation profile and clinical status is necessary. \(^{(2)}\)
- There is conflicting evidence suggesting fusidic acid may inhibit or induce CYP3A4. It is recommended that patients concomitantly treated with CYP3A4 bio-transformed medications and fusidic acid are monitored. \(^{(2)}\)

### COMMENTS
Due to incomplete absorption doses of the liquid formulation are greater than those for the tablets. \(^{(5)}\)

### MANUFACTURER SAFETY DATA SHEET (SDS)
To access to the Manufacturer SDS for this product, use the following link to ChemAlert.

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**Please note: The information contained in this guideline is to assist with the preparation and administration of sodium fusidate (fusidic acid). Any variations to the doses recommended should be clarified with the prescriber prior to administration**

**Related internal policies, procedures and guidelines**

- Antimicrobial Stewardship Policy
- ChAMP Empiric Guidelines
# References


5. Micromedex 2.0 [Internet]. Truven Health Analytics. 2017 [cited 21/09/2017].


# Useful Resources

**Neonatal Medication Protocols** (King Edward Memorial Hospital)

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This document can be made available in alternative formats on request for a person with a disability.

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