



Safety Notice 007/11

28 September 2011

Distributed to:

- Chief Executives
- Directors of Clinical Governance

Action required by:

- Directors of Clinical Governance

We recommend you also inform:

- Infectious Disease Physicians
- Medical and Surgical Department Heads
- Directors of Pharmacy
- Drug and Therapeutic Committees.
- Infection Control and Prevention Staff

Expert Reference Group

Information provided by:

- HAI Expert Advisory Committee Chair
- ACSQHC HAI Advisory Group

Clinical Safety Quality and Governance Branch

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BenPen™ (Benzylpenicillin)

Commonwealth Serum Laboratories (CSL) have advised that due to a delay in delivery from their overseas supplier, BenPen™ 600mg, BenPen™ 1.2g and BenPen™ 3g are on restricted supply. CSL anticipate that the restricted supply status on all BenPen™ presentations will remain in place until December 2011. CSL are the sole suppliers of benzylpenicillin in Australia. Local Health Districts/Networks and hospital distribution pharmacies have previously received advice on this matter from the NSW Health Department.

CSL have advised it will concentrate supply on hospitals and that orders will be prioritised to ensure hospitals can maintain supply of BenPen™ for as long as possible. The Healthcare Associated Infection Advisory Group of the Australian Commission on Safety and Quality in Health Care (ACSQHC) has advised that:

- There are appropriate substitute antibiotics for benzyl penicillin in all clinical conditions.
- The usual alternative will be ampicillin.
- There are a relatively small number of conditions where ampicillin is not appropriate.
- For conditions where ampicillin is not appropriate, preferred antibiotic treatment has been recommended by ACSQHC (attached).
- In the majority of cases the use of broad spectrum antibiotics will not be required.

CSL advises that for Doctor's Bag orders, alternate supply of Cilicaine (Procaine Penicillin Injection 1.5g), available from Aspen Pharma, may be used

Local Health Districts/Networks should:

- Distribute this notice and attachment to key stakeholders and all clinical departments.
- Assess the current status of benzylpenicillin available in each facility.
- Develop a local plan to manage the supply shortage, including the role of infectious disease specialists where treatment choices require clarification.
- Consider the ACSQHC advice on restricting the supply of benzylpenicillin to the treatment of key conditions.

Further information

For further information on ACSQHC advice, contact

- Dr Marilyn Cruickshank, Program Manager, HAI, ACSQHC, 9126 3586.

For further Product Information, contact

- CSL Customer Service on 1800 008 275.

Suggested Actions by Local Health Districts/ Networks

1. Assess the current status of local benzylpenicillin supplies to ensure parity of access
2. Ensure that this Safety Notice and attachments are distributed to all relevant stakeholders.
3. Develop and implement a local plan to manage the supply shortage.

Clinical advice concerning the shortage of benzylpenicillin

BACKGROUND

On the 20th September 2011 CSL Laboratories released a circular to hospitals advising of a delivery delay from overseas suppliers of benzylpenicillin.

CSL will be placing restrictions on supply to hospitals until December 2011. This affects all strengths (600mg, 1.2g, 3g)

Narrow-spectrum penicillins such as benzylpenicillin, procaine penicillin and benzathine penicillin are active against Gram-positive organisms (streptococci, enterococci and beta-lactamase negative *Staphylococcus aureus*). They are also active against a range of fastidious Gram negative bacteria, including beta-lactamase negative *Haemophilus* species and *Neisseria meningitidis*.

Parenteral benzylpenicillin (penicillin-G) is the mainstay for treatment of moderate to severe community-acquired pneumonia, streptococcal infections, neurosyphilis and various other serious infections.

GENERAL COMMENTS

There are appropriate substitute antibiotics for benzyl penicillin in all clinical condition.

In the majority of cases, the use of broad spectrum antibiotics will not be required to treat conditions for which benzyl penicillin is normally prescribed.

The use of the recommended alternate antibiotics means that the shortage of benzyl penicillin will not contribute to the wider spread of multi resistant pathogens.

RECOMMENDATIONS FOR ALTERNATIVE ANTIBIOTIC USE

These recommendations are made by the Australian Commission on Safety and Quality in Health Care following discussion with their HAI Advisory Committee.

1. For most clinical indications, ampicillin or amoxicillin injections can be safely substituted for benzylpenicillin. The general recommended dosage equivalence is:
 - a. Adult :1.2g benzylpenicillin = 1g ampicillin or 1g amoxicillin injection
 - b. Children: 60mg/kg benzylpenicillin = 50mg/kg ampicillin or 50mg/kg amoxicillin injection

Important exceptions and provisos are detailed in the attached table.

2. As there are no anticipated shortages for either procaine penicillin or benzathine penicillin, Central Australian Rural Practitioners Association (CARPA) remote area guidelines can be followed as written.
3. In the treatment presumptive meningococcal infection ampicillin or amoxicillin for IM/IV is recommended for use - see attached chart for dose recommendations.
4. A reserve stock of benzylpenicillin should be maintained for the treatment of congenital syphilis.

CONTACT

For further information contact Dr Marilyn Cruickshank
Program Manager, Healthcare Associated Infection, ACSQHC, 02 9126 3586

SPECIFIC CLINICAL SYNDROMES THAT REQUIRE ADDITIONAL CONSIDERATION

Syndrome or diagnosis	Recommendation (1.= preferred therapy; 2 = alternate therapy)	Comment
Acute meningitis, empiric treatment to include coverage of <i>Listeria monocytogenes</i>	1. Dexamethasone 10mg (child: 0.15mg/kg up to 10mg) IV starting before or with the first dose of antibiotic, PLUS Ampicillin * 2g (child: 50mg/kg up to 2g) IV, every 4 hours PLUS Ceftriaxone 2g (child: 50mg/kg up to 2g) IV, every 12 hours OR Cefotaxime* 2g (child: 50mg/kg up to 2g) IV, every 6 hours	For adults and children aged 3 months and more when coverage required for <i>Listeria monocytogenes</i> . Patients at risk from <i>Listeria</i> infection include: immunocompromised, adults more than 50 years of age, patients with a history of alcohol abuse or patients who are pregnant or debilitated.
Acute meningitis, directed treatment for: <i>Listeria monocytogenes</i> <i>Haemophilus influenzae</i> type B (betalactamase negative strains) <i>Streptococcus pneumoniae</i> (fully susceptible strains, MIC < 0.125 mg/L) <i>Streptococcus agalactiae</i>	1. Ampicillin* 2g (child: 50mg/kg up to 2g) IV, every 4 hours	For recommended durations of treatment, see TG: Antibiotic, Edition 14.
Endocarditis, empiric management	1. Ampicillin* 2g (child: 50mg/kg up to 2g) IV, every 6 hours PLUS Flu/dicloxacillin* 2g (child: 50mg/kg up to 2g) IV, every 4 hours PLUS Gentamicin * 4-6mg/kg IV, daily	See Therapeutic Guidelines for detailed child and other dosing instructions for gentamicin.
Endocarditis, Streptococcal (viridans group)	1. Viridans streptococci fully susceptible to penicillin (MIC 0.12mg/L or less), use: Ceftriaxone 2g (child 50mg/kg up to 2g) IV daily for 4 weeks.	For viridans streptococci with MIC > 0.12mg/L, seek clinical microbiologist or infectious diseases physician advice.
Meningococcal infection (presumptive)	1. Ampicillin* dose recommendations (for IV or IM usage) Child less than 1 year: 375mg; Child 1-9 years: 750mg Adult or child 10 years or more: 1.5g 2. Ceftriaxone 2g (Child: 50mg/kg up to 2g) IV, stat in remote areas	
Necrotizing fasciitis due to <i>Streptococcus pyogenes</i>	1. Cephazolin* 2g (child: 50mg/kg up to 2g) IV, every 8 hours PLUS Clindamycin or lincomycin	See TG: Antibiotic, Edition 14 for dosage instructions for clindamycin and lincomycin.
Neurosyphilis (adult)	1. Procaine penicillin 3g IM, daily together with probenecid 500mg, oral every 6 hours given for 10 – 14 days 2. Ceftriaxone 2g IV, daily for 10 – 14 days	There are no published trial evidence supporting use of ampicillin in neurosyphilis.

* Reduce dose in renal impairment.

Resource: Therapeutic Guidelines: Antibiotic 14th Edition