Benzylpenicillin sodium
600mg and 1200mg Powder for Injection
Technical Leaflet

PRODUCT SUMMARY
Qualitative and Quantitative Composition
Benzylpenicillin sodium is available as 600 mg and 1200 mg vials.
Pharmaceutical form
White crystalline, water-soluble solid powder for injection.

CLINICAL PARTICULARS
Therapeutic indications:
Benzylpenicillin is indicated for the treatment of infections caused by susceptible strains of the following organisms: Streptococci, staphylococci, Neisseria gonorrhoeae, meningococci, Haemophilus influenzae, Bordetella pertussis, Actinomyces israelii, Listeria monocytogenes.

Dosage and administration:
The dosage schedule applies to both intravenous and intramuscular injections.
1. Alternatives should be used for repeated injections.
2. Adults: 600 mg IM or IV (1-2 mega units) every 5-6 hours as required.
3. Children: 300 mg IV (or IM) every 8 hours.

Precautions and special precautions:
1. Benzylpenicillin sodium is used to treat the infections caused by:
   - some sexually transmitted infections (gonorrhoea and syphilis)
   - chest infections (bronchitis)
   - ear infections
   - eye infections
   - nose infections
   - throat infections
   - urinary infections
   - certain skin infections (abscesses)

2. Antibiotics can cause skin reactions (e.g. cellulitis) due to lack of supportive care.

3. Benzylpenicillin sodium is used to treat infections that are caused by:
   - benzylpenicillin-resistant Streptococcus pneumoniae
   - non-susceptible strains of Haemophilus influenzae
   - beta-lactamase-negative strains of Neisseria meningitidis

4. Benzylpenicillin sodium is used to treat infections that are caused by:
   - Staphylococcus aureus
   - Staphylococcus epidermidis
   - Streptococcus pyogenes
   - Streptococcus viridans

5. Benzylpenicillin sodium is used to treat infections that are caused by:
   - Listeria monocytogenes
   - Campylobacter species

6. Benzylpenicillin sodium is used to treat infections that are caused by:
   - Neisseria gonorrhoeae
   - Haemophilus influenzae
   - Actinomyces israelii

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   - Listeria monocytogenes
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    - Neisseria gonorrhoeae
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    - Actinomyces israelii


**Technical Leaflet (continued)**

### Effects on ability to drive and use machines

None.

### Undesirable effects

**Blood and Lymphatic System Disorders**

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**Respiratory System Disorders**

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**Cardiovascular System Disorders**

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**Gastrointestinal System Disorders**

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**Skin Disorders**

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### Susceptibility:

The prevalence of resistance may vary geographically and with time for selected infections. Local information on resistance is desirable, particularly when treating severe infections. The following table gives only approximate guidance on probability whether micro-organisms will be susceptible to *Benzylpenicillin* alone or not.

### Other information:

**known Resistance Mechanisms and Cross-resistance**

Penicillin resistance can be mediated by alteration of penicillin-binding proteins or by production of a beta-lactamase. Resistance to penicillin may be associated with cross-resistance to a minority of other beta-lactam antibiotics. See also relevant summaries in the yellow card scheme.

**Cefotaxime, ceftriaxone, ceftazidime, ceftepime and cefepime**

Penicillins are not cross-resistant with most cephalosporins.

**Cephalosporins**

Penicillins are not cross-resistant with most cephalosporins.

**Tetracyclines**

Penicillins are not cross-resistant with most tetracyclines.

**CHLORAMPHENICOL**

Penicillins are not cross-resistant with most tetracyclines.

**SAFETY AND TOLERABILITY**

Penicillins may cause allergic reactions, anaphylaxis, serum sickness and complications of physical or mental stress. We are conducting extensive tests to ensure the safety of this medicine.

### Breakdown:

The beneficial breakdown (British Society for Antimicrobial Chemotherapy, BSAC) for *Benzylpenicillin* sodium are as follows:

### Pharmacological properties

**Pharmacodynamic properties**

*Beta-lactamase-sensitive penicillins.*

**Adc code: J01C01.**

**General Properties:**

*Benzylpenicillin* sodium is a beta-lactam antibiotic. It is bactericidal by inhibiting bacterial cell wall biosynthesis.

### Precautions for storage

Store below 25°C.

### Marketing Authorisation Holder

Genus Pharmaceuticals, Linthwaite, Huddersfield, HD7 5QH, UK.

### Marketing Authorisation Numbers

PL 068310213 PL 068310224

### Date of first authorisation / renewal of authorisation

3 July 2008

### Date of (part) revision of the text

November 2020

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### 6. Further information

The active substance in *Benzylpenicillin* Injection is *Benzylpenicillin* sodium.

**What Benzylpenicillin Injection looks like and the contents of the pack**

*Benzylpenicillin* Injection is a white, crystalline powder, supplied in two strengths of 600mg and 1,200mg as a lyophilised plug in a rubber stoppered glass vial. The 60mg may be available in packs of 2 to 20 units. The 1,200mg is available in packs of 23.

### 7.58GB

PL 068310213 Benzylpenicillin Injection 600mg

PL 068310224 Benzylpenicillin Injection 1200mg

Marketing Authorisation Holder: Genus Pharmaceuticals, Linthwaite, Huddersfield, HD7 5QH, UK.

Manufacturers:

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### List of excipients

None.

### Incompatibilities

Benzylpenicillin sodium and solutions that contain metal ions should be administered separately.

### Benzylpenicillin sodium should not be administered in the same syringe/gene gun as amphotericin B, cimetidine, cytarabine, fluoroquinolones, hydrocortisone, metyrapone or promethazine since it is incompatible with these drugs.

### Shelf-life

Unopenped 36 months. The reconstituted product should be used immediately.

### Special precautions for storage

Store below 25°C.

### Nature and contents of container

Tubular type II glass vials sealed with teflon-lined rubber plugs with aluminium overcaps or plain teflon stoppers. This product is supplied in vials containing 600 mg and 1.2 g of powder in boxes containing 25 vials and “OP pack” containing 2 vials of 80 mg.

### Instructions for use/handling

After contact with skin: wash immediately with water. In case of contact with eyes: rinse immediately with plenty of water and seek medical advice if discomfort persists.

### Additional information

None.

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