Benzylpenicillin sodium 600mg and 1200mg Powder for Injection

Technical Leaflet

**PRODUCT SUMMARY**

Qualitative and Quantitative Composition

Benzylpenicillin sodium available as 600 mg and 1200 mg vials.

Pharmaceutical Form

White crystalline, water-soluble sterile powder for injection.

**CLINICAL PARTICULARS**

**Pharmaceutical Form**

Preparation of solutions:

- Pharmaceutical preparation
- Preparation of solutions:
- A suitable concentration is 600 mg (1 mega unit) should be dissolved in at least 10 ml of Sodium Chloride Injection BP or Water for Injections BP and 1200 mg (2 mega units) should be dissolved in at least 20 ml of Sodium Chloride Injection BP or Water for Injections BP. Sodium chlorate and/or heat failure may occur if benzylpenicillin sodium is administered in sodium containing vials to patients who suffer from renal failure and/or heart failure. Therefore, for such patients, benzylpenicillin sodium should not be reconstituted in sodium containing liquids such as Sodium Chloride Injection BP or Ringer's solution.

**Dosage and administration:**

- Intramuscular injection:
  - Doses up to 432 mg (7.2 mega units) per day may be necessary for patients with rapidly spreading gas gangrene.
  - High doses should be administered by intravenous infusion or injection, with intravenous doses in excess of 1.2 g (2 mega units) given slowly, taking at least one minute for each 300 mg (0.5 mega units) to avoid high levels causing irritation of the central nervous system and/or electrolyte imbalance.
  - High dose administration of benzylpenicillin sodium may result in hyperkalemia and hypokalemia unless the sodium content is taken into account.

- For the prevention of Group B Streptococcal disease of the newborn, a 3 g (5 mega units) starting dose should be given to the mother initially followed by 1.5 g (2.5 mega units) every 4 hours until delivery.

- Benzylpenicillin sodium has been taken by a large number of other penicillins in human milk have been detected.

- Benzylpenicillin sodium is also used for the prevention of infection in rheumatic fever (see section 4 - Special warnings, special precautions).

- Penicillins may interfere with:
  - Oral contraceptives
  - Coombs' tests
  - Tests for urinary or serum proteins
  - Tests which use bacteria e.g. Guthrie test

**Special warnings, special precautions**

- Benzylpenicillin sodium may cause cerebral irritation, convulsions and coma. Skin sensitivity may occur in persons handling the antibiotic and care should be taken to avoid contact with the substance.

**Suspicion meningococcal disease**

If meningococcal disease is suspected general practitioners should give a single dose of benzylpenicillin sodium, before transferring the patient to hospital, as follows:

- Adults and children over 10 years: 1,200 mg IV (or IM)
- Children 1-9 years: 600 mg IV (or IM)
- Children under 1 year: 300 mg IV (or IM)

**Novel injecting and provocative techniques**

Dosing should not be more frequent than every 8 or 12 hours in this age group, since renal clearance is reduced at this age and the mean half-life of benzylpenicillin may be as long as 3 hours. Since infants have been found to develop severe local reactions to intramuscular injections, intravenous treatment should preferably be used.

**Patients with renal insufficiency**

- For doses of 0.6-1.2 g (1-2 mega units) the dosing interval should be no more frequent than every 8-10 hours.
- For high doses e.g. 14.4 g (24 mega units) required for the treatment of serious infections such as sepsis, meningitis, the dosage and dose interval of benzylpenicillin sodium should be adjusted in accordance with the following schedule:

<table>
<thead>
<tr>
<th>Dosage (g/mega unit)</th>
<th>Dosing interval (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 1.2</td>
<td>12</td>
</tr>
<tr>
<td>1.2-2.0</td>
<td>8</td>
</tr>
<tr>
<td>&gt; 2.0</td>
<td>≤ 6</td>
</tr>
</tbody>
</table>

**The dose in the above table should be further reduced to 0.3 g (0.5 mega unit) every 8 hours if advanced liver disease is associated with severe renal failure.**

If haemodialysis is required, an additional dose of 0.3 g (0.5 mega units) should be given every 6 hours during the procedure.

**Elderly Patients**

Retention may be delayed in elderly patients and dose reduction may be necessary.

**Contraindications**

- Allergy to penicillins, hypersensitivity to any ingredient of the preparation.
- Cross allergy to beta-lactams such as cephalosporins should be taken into account.

**Special warnings, special precautions**

- 600 mg benzylpenicillin contains 1.84 mmol of sodium. Massive doses of benzylpenicillin sodium can cause hyperkalemia and sometimes hypokalemia. Use of a potassium-sparing diuretic may be helpful. In patients undergoing high-dose treatment for more than 5 days, electrolyte balance, blood counts and renal functions should be monitored.

**Prolonged use of benzylpenicillin may occasionally result in an overgrowth of non-susceptible organisms or yeast and patients should be observed carefully for superinfections.**

**Pseudomembranous colitis should be considered in patients who develop severe and persistent diarrhoea during or after receiving benzylpenicillin.**

- There is reduced excretion of methotrexate (and thereby increased risk of methotrexate toxicity) when used with benzylpenicillin sodium.

**Probenecid inhibits tubular secretion of benzylpenicillin sodium and so may be given to increase the plasma concentrations.**

- Penicillins may interfere with:
  - Anticoagulants (see section 6 - Further information).
  - Oral contraceptives
  - orally administered anti-inflammatory agents
  - Metabolism of levodopa
  - Methotrexate (see section 6 - Further information).

- Benzylpenicillin sodium has been taken by a large number of pregnant women and women of childbearing age without an increased risk of miscarriage or other direct or indirect harmful effects on the fetus having been observed.

- Although it is not known if benzylpenicillin sodium may be excreted into the breast milk of nursing mothers, it is actively transported from the blood to milk in animals and trace amounts of other penicillins in human milk have been detected.

**Package Leaflet: Information for the User**

Benzylpenicillin sodium 600mg and 1200mg Powder for Injection

Read all of this leaflet carefully before you start taking this medicine:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side-effects get serious, or if you notice any other side-effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Benzylpenicillin Injection is and what it is used for
2. How to use Benzylpenicillin Injection
3. Possible side effects
4. How to store Benzylpenicillin Injection
5. Further information

1. What Benzylpenicillin Injection is and what it is used for

- Benzylpenicillin sodium 600mg and 1200mg Powder for Injection is referred to as “Benzylpenicillin Injection.” In this leaflet, it contains benzylpenicillin sodium, also known as penicillin G.
- Benzylpenicillin sodium is one of a group of medicines known as penicillins, which are antibiotics. Antibiotics are used to kill the bacteria (germs) which cause infections.
- Benzylpenicillin sodium is used to treat infections of the:
  - ear
  - nose
  - throat
  - chest
  - skin
  - kidney
  - bones
  - joints
  - adenoids
  - sinusitis
  - meningitis
  - gonorrhoea
  - sciatica
  - meningitis
  - listeria (a type of food poisoning)
  - gonococcal infection (infection from animals)
  - pyoderma (an infection following animal bites)
  - severe lung diseases (an infection from tick bites)
  - acute rheumatic fever
  - infections caused by rat bites.

- Benzylpenicillin sodium is also used for the prevention of infection in rheumatic fever (see section 4 - Special warnings, special precautions).

2. How to use Benzylpenicillin Injection

Do not use Benzylpenicillin Injection if you:

- are allergic (hypersensitive) to benzylpenicillin sodium, any other benzylpenicillins or to any of the ingredients of this medicine.

Take special care with Benzylpenicillin Injection if you:

- suffer from other allergies, especially an allergy to medicines
  - are pregnant, breast-feeding or think you could be pregnant
  - have kidney problems
  - have any heart problems
  - are diabetic.

Using other medicines

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Take care if you are taking any of the following medicines:

- oral contraceptives
- probenecid (for the treatment of gout (inflammation of the joints, especially the big toe)
- methotrexate (for the treatment of certain cancers)
- allopurinol or sulfapyridine - treatments for gout
- neomycin - an antibiotic
- co-antibiotics - medicines that prevent blood clots
- oral hypoglycemic.

If you have any side effects or if you are at all concerned about anything, please consult your doctor.

**Please read the back of this leaflet.**
PHARMACEUTICAL PARTICULARS

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 or given as an antacid, vitamin, cytarabine, fluoxyzine, hydroxyzine, methyprsadinolone, or promethazine since it is incompatible with these drugs.

Shelf-life
Unexpired 36 months.

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 bromobutyl rubber plugs with aluminium overseals or plastic “flip-top” caps. The product is supplied in vials containing 650 mg and 1.2 g of powder in boxes containing 25 vials and “GP pack” containing 2 vials of 650 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.

MARKETING AUTHORISATION HOLDER
Genus Pharmaceuticals, Linthwaite, Huddersfield, HD7 5QH, UK.

MARKETING AUTHORISATION NUMBERS
PL 08631/0284
PL 08631/0285

DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION
3 July 2008

DATE OF (PARTIAL) REVISING OF THE TEXT
September 2016

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 (600mg and 1,200mg) as a lyophilisate in a rubber-stoppered glass vial. The 600mg vial is available in packs of 2 (GP pack) and 25. The 1.200mg vial is available in packs of 25.

POM
PL 08631/0283 Benzylpenicillin Injection 600mg
PL 08631/0284 Benzylpenicillin Injection 1200mg

Marketing Authorisation Heider and Manufacturer
Marketing Authorisation Heider: Genus Pharmaceuticals, Linthwaite, Huddersfield, HD7 5QH, UK.

Manufacturers:
Sandor GmbH, A-4050 Kundl, Tirol, Austria.
Genus Pharmaceuticals, Linthwaite, Huddersfield, HD7 5QH, UK.

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