PACKAGE LEAFLET: INFORMATION FOR THE USER

Benzylopenicillin 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 changes in vision not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Benzylopenicillin Injection is and what it is used for
2. Before you use Benzylopenicillin Injection
4. Possible side-effects
6. How to store Benzylopenicillin Injection
6. Further information

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

Benzylopenicillin sodium 600mg and 1200mg Powder for Injection is referred to as “Benzylopenicillin Injection” in this leaflet. It contains benzylopenicillin sodium, also known as penicillin G. Benzylopenicillin 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.

Benzylopenicillin sodium is used to treat infections of the:
- ear
- nose
- throat
- chest

It may also be used to treat:
- some sexually transmitted infections (gonorrhoea and syphilis)
- meningitis
- brain abscesses
- gangrene (ischaemia and death of tissue due to lack of blood supply)
- blood infections
- arthritis (an infection from animals)
- tetanus
- diphtheria (acute infectious disease of the respiratory tract)

Benzylopenicillin sodium is also used for the prevention of infection in newborn babies, especially Group B streptococcal infection.

2. Before you use Benzylopenicillin Injection

Do not use Benzylopenicillin Injection if you:
- are allergic (hypersensitive) to benzylopenicillin sodium, any other antibiotics (in particular other penicillins, cephalosporins or beta-lactams), or any of the other ingredients (see section 6. Further information).

Take special care with Benzylopenicillin Injection if you:
- suffer from other allergies, especially an allergy to medicines
- are pregnant, breast-feeding or think you could be pregnant
- have liver 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 sulfinpyrazone—treatments for gout (inflammation of the joints, especially the big toe)
- carbamazepine—treatments for epilepsy
- salicylates
- tricyclic antidepressants
- medicines that prevent blood clots
- oral hypoglycaemic agents.

Benzylopenicillin may make the effects of Benzylopenicillin last for longer. Benzylopenicillin can make it more likely to get side effects from methotrexate and can sometimes make oral contraceptives less effective, resulting in unwanted pregnancy.

Penicillins can interfere with the results of certain urine and blood tests.

Pregnancy and breast-feeding
Your medicine will be injected either intramuscularly (into the muscle) or intravenously (into a vein). Repeated injections will be given at different sites. Infants and intravenous may be given in serious respiratory tract and middle ear, etc.

Pharmaceutical Form

There are two routes of administration:

- Intramuscular injection:
- Intravenous injection:

Intramuscular injection: A suitable concentration is 600 mg (1 mega unit) intramuscularly in 10 ml of Sodium Chloride Injection BP or Water for Injections BP.

The dose in the above table should be further reduced to 200 mg (0.5 mega units) hourly if advanced liver disease is associated with severe renal failure.

If haemodilysis is required, an additional dose of 300 mg (0.5 mega units) should be given 6 hourly during the procedure.

Elderly Patients

Dosage 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 other beta-lactams such as cephalosporins may be taken into account.

Special warnings, special precautions

600 mg benzylpenicillin contains 1.68 mmol of sodium. Massive doses of benzylpenicillin sodium may cause hypernatraemia and hypokalaemia 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) loading dose should be given to the newborn immediately, followed by 1.8 g (3 mega units) every 4 hours until delivery.

For the prevention of infection in newborn babies, especially Group B streptococcal infection.

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

Penicillins may interfere with:
- Urinary glucose tests
- Tests for urinary or serum proteins
- Tests which use bacteria e.g. Guthrie test

Pregnancy and lactation

Benzylopenicillin sodium has been taken by a large number of pregnant women and women of childbearing age without an increase in malformations 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.

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. In this situation, even if Clostridium difficile is only suspected, administration of benzylpenicillin should be discontinued and appropriate treatment given.

Interaction with other medications and other forms of treatment

The efficacy of oral contraceptives may be impaired under concomitant administration of benzylpenicillin sodium, which may result in unwanted pregnancy. Women taking oral contraceptives should be aware of this and should be informed about alternative methods of contraception.

There is a reduced excretion of methotrexate and therefore increased risk of methotrexate toxicity when used with benzylpenicillin sodium.

Click to enlarge section

1. How to store Benzylpenicillin Injection

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Penicillins can interfere with the results of certain urine and blood tests.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

3. How to use Benzylopenicillin Injection

Your doctor will mix the benzylpenicillin sodium powder with an injection solution, which is usually water for injections or sodium chloride, before injecting it. (Sodium citrate injection will not be used if you have kidney or heart problems.)

Your medicine will be injected either intramuscularly (into the muscle) or intravenously (into a vein). Repeated injections will be given at different sites. Infants and infants will normally receive Benzylpenicillin into a vein.
Per day. The usual dose for children is 100mg per kg body weight.

More rarely, anaphylactic reactions have been reported (<0.05% treated patients).

Reversal System Disorders

Rare (0.01%-0.1%)

When very high doses of Benzylpenicillin Injection have been given, corrective measures will help protect the environment.

The prevalence of resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections.

The following table gives only approximate guidance on probabilities whether micro organisms will be susceptible to benzylpenicillin sodium or not.

<table>
<thead>
<tr>
<th>Type of Micro-organism</th>
<th>Susceptible</th>
<th>Intermediately susceptible</th>
<th>Resistant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aerobic Gram-negative bacilli</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemolytic streptococci</td>
<td>0-20%*</td>
<td>2-20%**</td>
<td>&gt;20%***</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>0%*</td>
<td>0%*</td>
<td>0%***</td>
</tr>
<tr>
<td><strong>Aerobic Gram-positive cocci</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>0%***</td>
<td>0%***</td>
<td>0%***</td>
</tr>
<tr>
<td>Group A streptococci</td>
<td>0%***</td>
<td>0%***</td>
<td>0%***</td>
</tr>
<tr>
<td><strong>Other microorganisms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clostridium perfringens</td>
<td>0%***</td>
<td>0%***</td>
<td>0%***</td>
</tr>
<tr>
<td>Clostridium tetani</td>
<td>0%***</td>
<td>0%***</td>
<td>0%***</td>
</tr>
<tr>
<td>Clostridium histolyticum</td>
<td>0%***</td>
<td>0%***</td>
<td>0%***</td>
</tr>
</tbody>
</table>

The daily dose may be divided into between two and six separate injections. Higher daily doses of up to 14,400mg and 43,200mg respectively may be used.

Suspected Meningitis

Benzylpenicillin is sometimes given as a single dose in cases of suspected meningitis. The usual dose is 1,200mg for adults and children over 10 years.

Meningitis:
The usual dose is 2,400mg every four hours for adults.

Prevention of infection during labour:

Benzylpenicillin is administered during labour for the prevention of infection specifically group B streptococcal infection in newborn babies, 3,000mg of benzylpenicillin sodium should be given to the mother followed by 1,500mg every four hours until the baby is delivered.

Adults with kidney problems

Your doctor will carry out some tests to check this. You may then be given a lower dose of benzylpenicillin injection. Lower doses may also be given to some elderly patients.

Children

The dose for babies and children is based on their weight. The usual dose for newborn babies is 50mg per kg body weight per day and for infants (1 to 4 weeks old) is 75mg per kg body weight per day. The usual dose for children is 100mg per kg body weight per day although higher doses of up to 4,000mg per day may be given.

4. POSSIBLE SIDE-EFFECTS

Like all medicines, Benzylpenicillin Injection can cause side-effects, although not everybody gets them.

Tell your doctor immediately if you get any of the following side-effects:

• skin rash or itchy skin
• difficulty in breathing or tightness of the chest
• pain or pressure of the head
• swelling of the eyelids, face or lips
• swelling or thickening of the tongue
• fever
• joint pains
• swollen lymph nodes.

The following side-effects have also been reported after either long-term use or with high-doses of your medicine:

• reduction in blood cell count and anaemias which might make you feel tired or dizzy
• low levels of potassium in the blood
• inflammation of the kidney
• skin irritation, fever, headache, sore throat, sore muscles and fast heartbeat particularly in patients being treated for syphilis (a sexually transmitted disease)
• diarrhoea, which may, rarely, have blood in it
• breath infections or with other germs
• fits (convulsions).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

5. HOW TO STORE BENZYLPCILLIN INJECTION

Keep out of the sight and reach of children.

Benzylpenicillin Injection vials should be stored below 25°C. Once the content of the vial has been mixed with an injection solution it should be used immediately.

They should not be kept for more than 60 minutes after mixing. If it is left longer than this it will no longer be effective. Do not use if the seal on the vial is broken or the vial has been accidentally dropped.

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Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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 800mg and 1,200mg as a lyophilised plug in a rubber stoppered glass vial. The 800mg vial is available in packs of 2 (GP pack) and 25. The 1,200mg vial is available in packs of 25.

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POM

PL 06831/0213 Benzylpenicillin Injection 800mg
PL 06831/0284 Benzylpenicillin Injection 1200mg

Marketing Authorisation Holder and Manufacturer

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

Marketing Authorisation Numbers

PL 06831/0213
PL 06831/0284

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