

PACKAGE LEAFLET: INFORMATION FOR THE USER

Benzylpenicillin sodium 600 mg and 1200 mg powder for solution for injection or infusion

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any side-effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Benzylpenicillin Injection is and what it is used for
2. What you need to know before you use Benzylpenicillin Injection
3. How to use Benzylpenicillin Injection
4. Possible side effects
5. How to store Benzylpenicillin Injection
6. Contents of the pack and other information

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

Benzylpenicillin sodium 600 mg and 1200 mg powder for solution for injection or infusion 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 Injection is used to treat **infections of the ear, nose, throat, chest, heart, bones and skin.**

It may also be used to treat:

- some sexually transmitted infections (gonorrhoea and syphilis),
- meningitis,
- brain abscesses,
- gangrene (decay and death of tissue due to lack of blood supply),
- blood infections,
- anthrax (an infection from animals),
- tetanus,
- diphtheria (acute infections/disease of the respiratory tract),
- listeria (a type of food poisoning),
- leptospirosis (an infection from animals),
- pasteurellosis (an infection following animal bites),
- severe Lyme disease (an infection from tick bites),
- actinomycosis (an infection caused by trauma/surgery)
- some infections caused by rat bites.

Benzylpenicillin Injection is also used for the prevention of infection in newborn babies (specifically group B streptococcal infection).

2. What you need to know before you use Benzylpenicillin Injection

Do not use Benzylpenicillin Injection if you:

- are allergic to benzylpenicillin sodium, any other antibiotics (in particular other penicillins, cephalosporins or beta-lactams).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using this medicine if any of these apply to you:

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

Other medicines and Benzylpenicillin Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly any of the following medicines:

- probenecid for the treatment of gout (inflammation of the joints, especially the big toe). Probenecid may make the effects of this injection last for longer
- methotrexate for the treatment of certain cancers. This injection may make it more likely to get side-effects from methotrexate
- allopurinol or sulfinpyrazone (treatments for gout)
- neomycin (an antibiotic)
- anti-coagulants (medicines that prevent blood clots)
- oral typhoid vaccine

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine.

Benzylpenicillin Injection contains sodium:

Benzylpenicillin Injection 600mg contains 38.7mg (1.68mmol) of sodium (main component of cooking/table salt) in each dosage unit. This is equivalent to 1.93% of the recommended maximum daily dietary intake of sodium for an adult.

Benzylpenicillin Injection 1200mg contains 77.4mg (3.36 mmol) of sodium (main component of cooking/table salt) in each dosage unit. This is equivalent to 3.86% of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need 5 or more dosage units of 1200mg benzylpenicillin (or 10 or more dosage units of 600mg benzylpenicillin) for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to use Benzylpenicillin Injection

Your doctor or nurse will prepare your injection. They will inject this into a muscle (intramuscularly) or into a vein (intravenously). Repeated injections will be given at different sites.

Infants and diabetics will normally receive the injection into a vein.

Adults

The usual dose is 600 mg to 3,600 mg daily.

For severe infections such as meningitis and gangrene, higher daily doses of up to 14,400 mg and 43,200 mg respectively may be used.

Suspected Meningitis

This medicine is sometimes given as a single injection 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

If the injection is administered during labour for the prevention of infection in newborn babies (specifically group B streptococcal infection), 3,000mg 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 this 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 50 mg per kg of their body weight per day.

For infants (1 to 4 weeks old), the usual dose is 75 mg per kg of their body weight per day.

The usual dose for children is 100 mg per kg of their body weight per day although higher doses of up to 4,000 mg per day may be given.

The daily dose may be divided into between two and six separate injections. Higher doses for severe infections are usually given by slow intravenous infusion (drip).

Meningitis

The usual dose is 180-300mg per kg per day (up to 12g per day) for children up to 12 years old, 150mg per kg per day for infants (1 to 4 weeks old) and 100mg per kg per day for newborn babies.

Premature babies and neonates

Lower doses may also be given to these groups.

If you take more Benzylpenicillin Injection than you should

Irritation of the brain and shaking fits (convulsion) have been seen in patients when very high doses of this medicine have been given by mistake, in particular to patients with poor kidney function.

4. Possible side effects

Like all medicines, this medicine 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
- puffiness of the eyelids, face or lips
- swelling or redness 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 anaemia, which might make you feel tired or dizzy
- low levels of potassium in the blood
- high levels of sodium 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
- thrush or other infections
- fits (convulsions).

Other side effects (it is not known how frequently these side effects may occur):

- AGEP – Acute Generalized Exanthematous Pustulosis with symptoms such as severe drug skin reactions with or without reddening of the skin, fever, pustules
- maculo-papular rash (flat and red area on the skin)
- rash morbilliform (rash that looks like measles),
- itching
- erythema (inflammatory reddening of the skin)
- angioedema (swelling of the skin, mucosa and subcutaneous tissue, generally located on the face, mouth or tongue)
- thrombocytopenia (reduced blood levels of platelets)
- anaemia (reduced blood levels of red blood cells)
- metabolic encephalopathy (neurological disorders with convulsions and loss of consciousness).

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Benzylpenicillin Injection

Keep this medicine out of the sight and reach of children.

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

Do not use this medicine after the expiry date which is stated on the carton and label after 'Exp'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Benzylpenicillin Injection contains

The active substance is benzylpenicillin sodium 600 mg or 1200 mg.

What Benzylpenicillin Injection looks like and contents of the pack

Benzylpenicillin Injection is a white, crystalline powder supplied in two strengths (600 mg and 1200 mg) in a rubber stoppered glass vial.

Pack sizes: 10 vials.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for medical or healthcare professionals only

Preparation of solutions:

Only freshly prepared solutions should be used. Reconstituted solutions of benzylpenicillin sodium are intended for immediate administration.

Intravenous Injection:

600mg vial: Dissolve 600 mg (1 mega unit) in 4 ml of Water for Injection or Sodium Chloride Injection (displacement value: approximately 0.4 ml).

1200mg vial: Dissolve 1200 mg (2 mega units) in at least 8 ml of Sodium Chloride Injection or Water for Injection (displacement value: approximately 0.8 ml).

For lower concentrations, draw up the entire contents of the vial and dilute to 10 ml (600mg vial) or 20 ml (1200mg vial) with Water for Injection or Sodium Chloride Injection.

Intravenous Infusion:

600mg vial: Dissolve 600 mg (1 mega unit) in at least 10 ml of Sodium Chloride Injection or Water for Injection.

1200mg vial: Dissolve 1200 mg (2 mega units) in at least 20 ml of Sodium Chloride Injection or Water for Injection.

Intramuscular injection:

600mg vial: Dissolve 600 mg (1 mega unit) in 1.6 to 2.0 ml of Water for Injection.