

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 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. Before you use Benzylpenicillin Injection
3. How to use Benzylpenicillin Injection
4. Possible side-effects
5. How to store Benzylpenicillin Injection
6. 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
- heart
- bones
- 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 infections following animals bites)
- severe Lyme disease (an infection from tick bites)
- actinomycosis (an infection caused by trauma/surgery)
- some infections cause by rat bites.

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

2. BEFORE YOU USE BENZYLPENICILLIN INJECTION

Do not use Benzylpenicillin Injection if you:

- are allergic (hypersensitive) to benzylpenicillin 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 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 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:

- probenecid for the treatment of gout (inflammation of the joints, especially the big toe)
- methotrexate for the treatment of certain cancers
- allopurinol or sulfapyrazone - treatments for gout
- neomycin - an antibiotic
- anti-coagulants - medicines that prevent blood clots
- oral typhoid vaccine.

Probenecid may make the effects of Benzylpenicillin last for longer.

Benzylpenicillin can make it more likely to get side-effects from methotrexate

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.

Sodium Content

600mg benzylpenicillin contains 38.7mg (1.68mmol) 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.

1200mg benzylpenicillin 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 will mix the benzylpenicillin sodium powder with an injection solution, which is usually water for injections or sodium chloride, before injecting it. (Sodium chloride 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 diabetics will normally receive Benzylpenicillin into a vein.,

Adults

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

For severe infections such as meningitis and gangrene, 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:

If Benzylpenicillin is administered during labour for the prevention of infection (specifically group B streptococcal infection) in newborn babies, 3,000mg of Benzylpenicillin 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.

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 Benzylpenicillin Injection have been given by mistake, in particular to patients with poor kidney function.

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
- 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 anaemias 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 infections with other germs
- 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BENZYL PENICILLIN 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 use a bottle after the expiry date printed on the bottle label. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

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 lyophilised plug 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 06831/0213 Benzylpenicillin Injection 600mg
PL 06831/0284 Benzylpenicillin Injection 1200mg

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:

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

Manufacturers:

Sandoz GmbH, A-6250 Kundl, Tirol, Austria.

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

This leaflet was last revised in August 2021