

Crystapen 600mg Powder for Solution for Injection or Infusion

Benzylpenicillin Sodium

Package leaflet

This leaflet tells you about the medicine you are receiving. It does not contain all the information about your medicine. If you have any questions or are unsure about anything, ask your doctor or pharmacist.

What does your medicine contain?

Crystapen Injection is available in 600mg vials, which contain 600mg of benzylpenicillin sodium, as the active ingredient in each vial. Benzylpenicillin sodium is also known as penicillin G.

The 600mg vial is available in packs of 2 and 25 vials. Not all pack sizes may be marketed.

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 infection. Benzylpenicillin sodium 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 (e.g. gonorrhoea and syphilis), meningitis, brain abscesses, gangrene, blood infections, anthrax, tetanus, diphtheria, 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) and some infections caused by rat bites. Benzylpenicillin sodium is also used for the prevention of infection in newborn babies (specifically group B streptococcal infection).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Clonmel Healthcare Ltd., Waterford Road, Clonmel, Co. Tipperary, E91 D768, Ireland.

Manufacturers:

Sandoz GmbH, A-6250 Kundl, Tirol, Austria

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

Before your medicine is used

IF THE ANSWER IS **YES** TO ANY OF THE FOLLOWING QUESTIONS, PLEASE TELL YOUR DOCTOR BEFORE YOUR MEDICINE IS USED:

- Are you pregnant, think you might be pregnant, or intending to become pregnant?
- Are you a breast-feeding mother?
- Have you ever had an allergic reaction to benzylpenicillin sodium or any other antibiotic (in particular other penicillins, cephalosporins or beta-lactams)?
- Do you suffer from other allergies, especially an allergy to medicines?
- Do you have kidney problems?
- Do you have liver problems?
- Do you have any heart problems?
- Are you diabetic?
- Are you currently taking any other medication, particularly probenecid or methotrexate?

This medicinal product contains 1.68 mmol sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

How your medicine is given

Crystapen Injection is a white powder. The doctor or nurse will mix the powder with an injection solution, which is usually Water for Injections or Sodium Chloride Injection, 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 Crystapen into a vein.

The dose for adults may be 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.

The dose for babies and children is based on their weight. The usual dose for newborn babies is 50mg/kg body weight per day and for infants (1 to 4 weeks old) is 75mg/kg body weight per day. The usual dose for children is 100mg/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).

Crystapen 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, 600mg for children (1-9 years) and 300mg for infants (under 1 year), by intramuscular or intravenous injection.

For the treatment of meningitis the dose is 2.4g every 4 hours for adults and children over 12 years, 180-300mg/kg/day (up to 12g/day) for children up to 12 years, 150mg/kg/day for infants (1-4 weeks old) and 100mg/kg/day for newborn babies.

If Crystapen is administered during labour for the prevention of infection (specifically group B streptococcal infection) in newborn babies, 3,000mg of Crystapen should be given to the mother followed by 1,500mg every 4 hours until the baby is delivered.

If you have kidney problems, your doctor will carry out some tests to check this. You may then be given a lower dose of Crystapen Injection. Lower doses may also be given to some elderly patients, premature babies and neonates.

Taking Crystapen with other medicines

Always tell your doctor if you are taking any medication, particularly probenecid or methotrexate. Probenecid may make the effects of Crystapen last for longer. Crystapen can make it more likely to get side effects from methotrexate.

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

If you have too much medicine

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

Side Effects

All medicines may sometimes cause side effects in some people. Tell your doctor immediately if you think your medicine is making you feel unwell, or, if you get any of the following:

Allergy to benzylpenicillin sodium which may occur as:

- 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 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 heart beat particularly in patients being treated for syphilis
- Diarrhoea, which may, rarely, have blood in it
- Thrush or infections with other germs
- Fits (convulsions)

Rare (may affect up to 1 in 1,000 people):

- diarrhoea

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:

HPRRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

Storage of your medicine

Crystapen 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.

Your medicine should always be used before the expiry date which is printed on the carton and the vial label.

Your doctor will know how to store your medicine.

Keep out of the sight and reach of children.

Do not throw this leaflet away as you may want to read it again.

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