1.3 Product Information

1.3.1 SPC, Labelling & Package Leaflet

Patient Information Leaflet

Package leaflet: Information for the user

Benzylpenicillin benzathine 1.2 Million I.U. powder for suspension for injection
Benzylpenicillin benzathine 2.4 Million I.U. powder for suspension for injection
Benzylpenicillin benzathine

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 or pharmacist.
- This medicine has been prescribed for you only. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What benzylpenicillin benzathine is and what it is used for
2. What you need to know before benzylpenicillin benzathine is used
3. How benzylpenicillin benzathine is used
4. Possible side effects
5. How to store benzylpenicillin benzathine
6. Contents of the pack and other information

1. What benzylpenicillin benzathine is and what it is used for

This medicine contains benzylpenicillin benzathine, which is one of a group of medicines known as penicillins (“antibiotics”). Antibiotics are used to kill the bacteria (germs) which cause infections.

Benzylpenicillin benzathine is used for the treatment of:
- erysipelas (skin infection)
- syphilis
- tropical infectious diseases of the skin, caused by bacteria of the *Treponema* species, such as yaws or pinta

Benzylpenicillin benzathine is also used to prevent the following diseases:
- rheumatic fever
- poststreptococcal glomerulonephritis (a specific form of kidney inflammation)
- erysipelas (skin infection)

2. What you need to know before benzylpenicillin benzathine is used

Do not use benzylpenicillin benzathine if:
- you are allergic to penicillins or any of the other ingredients of this medicine (listed in section 6).
- you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or neck.

Warnings and precautions
Talk to your doctor or pharmacist before benzylpenicillin benzathine is used if:
- you have ever had an allergic reaction to other antibiotics like penicillin or other beta-lactam antibiotics.
- if you have kidney problems (your doctor may need to adapt the dose of this medicine).
- if you have liver problems.

Benzylpenicillin benzathine should not be used in tissues with poor blood flow.

If allergic symptoms occur (e.g. skin rash, itching, shortness of breath), tell a doctor immediately. Before treatment, a hypersensitivity test should be performed if possible. If an allergic reaction occurs, your doctor will stop your treatment and, if necessary, start appropriate therapy.

As a possible cross-allergy should be considered in patients with hypersensitivity to cephalosporins, please tell your doctor if you have already had a previous allergic reaction to certain antibiotics (cephalosporins).

If you have already been diagnosed with an allergy and/or allergic asthma or hay fever, you should tell your doctor. Severe immediate allergic reactions are possible even when the drug is administered for the first time. Based on general principles, in some cases, you will remain under observation for at least half an hour after the medicine has been administered in case an acute allergic reaction should occur. If an allergy occurs, the doctor will take appropriate measures. Treatment with benzylpenicillin benzathine must be stopped immediately.

When treating syphilis, a reaction to the bacterial toxins may occur, which lasts up to several days (Jarisch-Herxheimer reaction, see section 4). Typical symptoms are sudden fever (sometimes with chills), pale skin; followed by skin redness, headache, painful muscles and joints or tiredness. To suppress or alleviate a Jarisch-Herxheimer reaction, your doctor will start appropriate therapy.

Dose adjustments are necessary in patients with impaired kidney function and in patients with impaired liver function (see section 3).

In long-term treatment (more than a single dose), your doctor may arrange for checks on your blood count and liver and kidney function tests. Please make sure that you attend the check-ups prescribed by the doctor.

As with other antibiotics, therapy with benzylpenicillin benzathine may also lead to the overgrowth of non-susceptible germs. Contact your doctor if you get, for example, a fungal infection.

During treatment with antibiotics, including benzylpenicillin benzathine, diarrhoea may occur, even several weeks after you stopped your therapy. In case of severe or persistent diarrhoea, or if you notice that your stools contain blood or mucus, contact your doctor immediately. The therapy with benzylpenicillin benzathine must be stopped immediately, as it can be life-threatening. Do not take any medications which stop or slow down the bowel movements.

If neurological involvement cannot be ruled out in patients with congenital syphilis, forms of penicillin that reach a higher level in cerebrospinal fluid should be used.

Decreased elimination of povidone (one excipient included in this drug) should be considered in case of impairment of kidney function. It cannot be excluded that in very rare cases an accumulation of povidone or a local deposition and formation of granulomas (inflammation) may occur, which may be confused with tumours.

An effect on laboratory test results should also be considered (see also section 4).

Other medicines and benzylpenicillin benzathine
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Caution should be exercised when administering benzylpenicillin benzathine at the same time as the following medicines:
- probenecid, a medicine used to treat gout.
- methotrexate, a medicine used in chemotherapy. The combination with methotrexate is not recommended.
- anticoagulants: medicines used to thin the blood.

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

Pregnancy
Benzylpenicillin benzathine can be used during pregnancy after appropriate diagnosis and careful consideration of the benefits and risks by the prescribing doctor.

Breast-feeding
Small amounts of benzylpenicillin benzathine, the active substance, pass into breast milk.

Although no side effects have been reported to date in young infants fed on breast milk, the possibility of sensitisation or interference with the gut flora must nevertheless be considered. In the case of diarrhoea, candidiasis (fungal infection) or rash in the child, immediately ask your doctor for advice, because these disorders in the child could be due to benzylpenicillin benzathine.

In young infants also being fed on baby food, mothers receiving benzylpenicillin benzathine should express and discard their breast milk. They can start breast-feeding again 24 hours after completion of treatment.

Driving and using machines
This medicine can impair responsiveness and the ability to drive.

Due to the occurrence of possible serious side effects (e.g. anaphylactic shock with collapse and allergic-like reactions (e.g. stomach upsets), see section 4), benzylpenicillin benzathine can have a major influence on the ability to drive and use machines.

Benzylpenicillin benzathine contains phospholipids from the soya lecithin and sodium
This medicine contains phospholipids from soya lecithin. If you are allergic to peanut or soya, do not use this medicinal product. This medicine contains less than 1 mmol sodium (23 mg) per vial 1.2 Million I.U. and 2.4 Million I.U., that is to say essentially 'sodium-free'.

3. How benzylpenicillin benzathine is used

Benzylpenicillin benzathine is administered by your doctor, nurse or pharmacist.

The recommended dose is:
General treatment:
- Adults and adolescents: 1.2 Million I.U.
- Children (> 30 kg body weight): 1.2 Million I.U.
- Children (<30 kg body weight): 0.6 Million I.U.

Duration of treatment: Single dose

Treatment of syphilis:

- Primary and secondary stage
- Adults and adolescents: 2.4 Million I.U.
- Children: 50,000 IU per kg body weight, but not more than 2.4 Million I.U.

  Duration of treatment: Single dose (If clinical symptoms return or laboratory findings remain strongly positive, treatment should be repeated.)

- Late-stage syphilis (latent seropositive syphilis)
- Adults and adolescents: 2.4 Million I.U.
- Children: 50,000 IU per kg body weight, but not more than 2.4 Million I.U.

  Duration of treatment: Once weekly for 3 weeks

- Treatment of congenital syphilis (without neurological involvement)
- Newborns and infants: 50,000 IU / kg body weight

  Duration of treatment: Single dose

Treatment of tropical infectious skin diseases (yaws, pinta):

- Adults and adolescents: 1.2 Million I.U.
- Children (> 30 kg body weight): 1.2 Million I.U.
- Children (< 30 kg body weight): 0.6 Million I.U.

Duration of treatment: Single dose

Prevention of rheumatic fever, poststreptococcal glomerulonephritis and erysipelas:

- Adults and adolescents: 1.2 Million I.U.
- Children (> 30 kg body weight): 1.2 Million I.U.
- Children (< 30 kg body weight): 0.6 Million I.U.

Duration of treatment:

a) without heart involvement: at least 5 years, or up to 21 years of age every 3-4 weeks.
b) temporary heart involvement: at least 10 years, or up to 21 years of age every 3-4 weeks.
c) persistent heart involvement: at least 10 years or up to 40 years of age every 3-4 weeks; life-long treatment is sometimes necessary.

Special patient groups (impaired kidney function or impaired liver function)
The dosage and dosing interval will be determined by your doctor. If you have any questions on your dosage, please contact your doctor.

Method of administration
The preparation may only be injected into muscle (intramuscular administration).

The injection must not be administered into tissue with poor blood flow. In case of repeated intramuscular application, the site of injection site must be changed.

Severe local reactions may occur during intramuscular administration, especially in young children. For this reason, other treatments such as a different penicillin formulation can be used where possible.

If you have been given more benzylpenicillin benzathine than should you should have been given
At extremely high doses, penicillins can cause muscular spasms or seizures. If overdose is suspected, talk to a doctor immediately for advice.

If your doctor has forgotten to give you benzylpenicillin benzathine
If you think that you have not been given a dose, talk to your doctor immediately.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects (may affect up to 1 in 10 people)
- Fungal infection (candidiasis)
- Diarrhoea
- Feeling sick (nausea)
- Changes in certain test and investigation results performed by your doctor.

Uncommon side effects (may affect up to 1 in 100 people)
- Inflammation of the lining of the mouth (stomatitis) and of the tongue (glossitis)
- Being sick (vomiting)

Rare side effects (may affect up to 1 in 1,000 people)
- Allergic reactions, including:
    - nettle rash (urticaria).
    - swelling (angioedema)
    - skin reactions (erythema multiforme, exfoliative dermatitis)
    - fever
    - painful joints (arthralgia)
    - anaphylactic shock with collapse and asthma, skin bleeding (purpura) and gastrointestinal complaints (anaphylactoid reactions)
- kidney disease (nephropathy)
- kidney inflammation (interstitial nephritis)

Very rare side effects (may affect up to 1 in 10,000 people)
- certain blood disorders (so called haemolytic anaemia, leukopenia, thrombocytopenia, agranulocytosis)

Not known (frequency cannot be estimated from the available data)
- serum sickness
- inflammation of the large intestine (pseudomembranous colitis (see also section 2))
- liver inflammation (hepatitis)
- impairment of bile flow (cholestasis)
- pain at the injection site
- injection site infiltrates
- penicillin psychosis (Hoigné and Nicolau Syndrome)

When treating syphilis, a reaction to the bacterial toxins may occur, which lasts up to several days (Jarisch-Herxheimer reaction, see section 2). Typical symptoms are sudden fever (sometimes with chills), pale skin; followed by skin redness, headache, painful muscles and joints or tiredness. To suppress or alleviate a Jarisch-Herxheimer reaction, your doctor will start appropriate therapy.

It cannot be ruled out that, in very rare cases and due to the povidone content, povidone may accumulate in the reticuloendothelial system (RES) or local deposits and foreign body granuloma (inflammation) may occur, which may be confused with tumours.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (website: 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 benzathine

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

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

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What benzylpenicillin benzathine contains
The active substance is benzylpenicillin benzathine.

The other ingredients are: soya lecithin; polysorbate 80; carmellose sodium; sodium citrate, anhydrous; and povidone.

What benzylpenicillin benzathine looks like and contents of the pack
Powder in a glass vial for suspension for injection in a carton.
Pack of 1 vial.

Marketing Authorisation Holder
Brancaster Pharma Limited
Church House, 48 Church Street
Reigate
Surrey, RH2 0SN
United Kingdom

Manufacturer
Haupt Pharma Latina
Strada Statale 156 dei Monti Lepini
04100 Borgo San Michele LT - Italy

This leaflet was last revised in 11/2025.

Advice/medical education
Antibiotics are used to cure bacterial infections. They are ineffective against viral infections. If your doctor has prescribed antibiotics, you need them precisely for your current illness. Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective. Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect the appropriate:
- dosage

- schedule of dosing
- duration of treatment.

Consequently, to preserve the efficacy of this drug:

1. Use antibiotics only when prescribed.
2. Strictly follow the prescription.
3. Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
4. Never give your antibiotic to another person; it may not be appropriate to her/his illness.
5. After completion of treatment, return all unused drugs to your pharmacist to ensure they will be disposed of correctly.

The following information is intended for healthcare professionals only

Method of administration

The preparation is strictly for intramuscular injection (see SmPC).

The injection must not be administered into tissue with reduced perfusion (see SmPC).

This medicine should be administered by deep intramuscular injection into the upper, outer quadrant of the gluteus maximus or Hochstetter's ventrogluteal field, with the needle pointing towards the iliac crest or according to von Hochstetter's method. The puncture should be as vertical to the skin surface as possible and the injection as far away from major vessels as possible. In all events, aspiration must be performed prior to the injection. If aspiration of blood or pain occurs during the injection, it must be discontinued.

In children, the mid-lateral thigh muscles (quadriceps femoris) are recommended as an injection site. The deltoid muscle is only suitable if it is well formed; in this case, attention must be paid to the radial nerve.

In infants and young children, the peripheral area of the upper outer quadrant of the gluteal region should be used as the area for injection only in exceptional cases (e.g. widespread burns), in order to avoid sciatic nerve lesions.

The injection should be given as slowly as possible and only with the application of low pressure. “Rubbing” after the injection should be avoided.

Clinical practice guidelines recommend the reconstitution of benzathine benzylpenicillin with local anaesthetics, such as 1% Lidocaine Injection BP, to reduce pain at the injection site. Users should follow local clinical protocols.

Incompatibilities
Data on compatibility are available with water for injections and lidocaine.

Shelf-life after reconstitution
The medicine should be used immediately after reconstitution.

Special precautions for disposal and other handling
The suspension must be prepared aseptically.

Studies on numerous formulations of benzylpenicillin benzathine have identified an issue that aggregation of particles in the reconstituted suspension occurs in a small proportion of samples tested.

Difficulty with reconstitution has been reported with Benzylpenicillin benzathine 2.4 Million I.U. powder for suspension for injection. The following instructions concerning reconstitution should be followed to minimise reconstitution issues:

- introduce the diluent into the vial of powder using a needle suitable for reconstitution (such as a blunt filter needle (18G));
- agitate this suspension carefully for at least 40 seconds until a homogeneous suspension is obtained.

The product should be used immediately after reconstituting the suspension. If there is any delay in using the suspension the suspension should be gently agitated again prior to drawing up the suspension into the syringe.

Please note that should a blockage occur during withdrawal of reconstituted product from the vial, the vial concerned should be discarded and a new vial used to administer the prescribed dose to the patient.

The suspension for injection is intended for single use only.

After drawing the suspension into the syringe for administration using the needle suitable for reconstitution, change this needle for a new needle suitable for intramuscular administration: a needle of a diameter of at least 700µm (needle gauge: 22G, 21G or 20G) for intramuscular injection is preferred.

Because of the high concentration of suspended material, the needle may become blocked if intramuscular injection of the reconstituted product to the patient is not made at a slow, steady rate.

If a blockage is observed during intramuscular administration, the blocked needle should be replaced with a new needle of the same diameter and administration of the remaining dose may then continue.

Prior to injection, intravascular administration should be excluded by aspiration. The injection site should be changed with repeated injections.