Date: 13-06-2026

Direct Healthcare Professional Communication (DHPC)

PENICILIN G DRASELNÁ SOĽ BBP (Penicillin G Potassium): Foreign-language in outer packaging and a missing English Patient Information Leaflet (PIL).

Dear Healthcare Professional,

Enmaeyat Trading Company in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform healthcare professionals of the following important information in accordance with the requirements of the Saudi Food and Drug Authority (SFDA).

Summary:

- A quality defect has been identified in Penicillin G Potassium 1 MIU (Batch No. 2404059).
- The defect involves foreign-language outer packaging and a missing English Patient Information Leaflet (PIL).
- This communication is being issued in accordance with SFDA requirements.

Further information on the safety concern and recommendations:

A unit from Batch No. 2404059 of Penicillin G Potassium 1 MIU was reported to contain foreign-language outer packaging and a missing English Patient Information Leaflet (PIL).

Healthcare professionals are advised to verify the availability of the enclosed English PIL and to ensure that healthcare personnel are aware of the product information provided therein.

Placing the risk in context of the benefit:

The reported issue is limited to labelling and leaflet presentation and does not affect the product's quality, safety, or efficacy.

Further information:

Additional information will be communicated if further findings become available.

Call for reporting:

Healthcare professionals are encouraged to report any suspected adverse reactions or quality defects through The National Pharmacovigilance Centre (NPC) at SFDA:

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

Website: https://ade.sfda.gov.sa

- SFDA Call Centre: 19999
- E-mail: npc.drug@sfda.gov.sa

Company Contact Point:

Name: Mohammed Alhajri QPPV

Email: < PV@enmaeyat.com.sa>

Phone: <0500312000>

Annexes:

- English Patient Information Leaflet (PIL)

Best Regards

Talal Alzahrani

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

PENICILLIN G POTASSIUM SALT BBP 1 MIUPENICILIN G POTASSIUM SALT BBP 5 MIU

Powder for solution for injection of benzylpenicillin, potassium salt

Read the entire package leaflet carefully before you start using this medicine because it contains information that is important to you.

- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your doctor, pharmacist, or nurse.
- This medication is prescribed only for you. Don't give it to anyone else. It could harm them, even if their symptoms are the same as yours.
- If you experience any side effects, talk to your doctor, pharmacist, or nurse. This also applies to any side effects not listed in this leaflet. See section 4.

In this booklet you will learn:

1. What is penicillin G BBP potassium salt and what is it used for?
2. What you need to know before you start using PENICILLIN G POTASSIUM SALT BBP
3. How to use PENICILLIN G POTASSIUM SALT BBP
4. Possible side effects
5. How to store PENICILLIN G POTASSIUM SALT BBP
6. Package Contents and Other Information

1. What is PENICILLIN G POTASSIUM SALT BBP and what is it used for?

Benzylpenicillin, an injectable potassium salt, is very soluble in water. It is a basic bactericidal antibiotic with a broad medium spectrum and short duration of action. Benzylpenicillin, potassium salt, is absorbed very quickly after intramuscular administration and reaches maximum blood concentration within 15-30 minutes. The level then drops rapidly and after 4 hours is below the effective concentration.

It penetrates well into most tissues and is found primarily in extracellular fluid. Little penetrates the cerebrospinal fluid and the aqueous humor of the eye. However, in case of inflammation (meningitis), it penetrates the cerebrospinal fluid (and also other body fluids) to a significantly greater extent and more quickly. It does not penetrate sufficiently into purulent foci, ischemic areas (lack of blood supply) and necrotic (dead) tissues. The biological half-life is about half an hour, but in case of anuria (interruption of urine production) it is prolonged up to 7-10 hours. It is excreted in breast milk.

Antimicrobial spectrum: very effective against pyogenic streptococci and other hemolytic streptococci, pneumococci, gonococci and meningococci, corynebacteria, listeria,

Erysipelothrix insiddiosa, anthrax bacillus, actinomycetes, *Clostridium tetani* and anaerobic clostridia; Also against moraxellae, *Treponema pallidum and* most strains of leptospira.

PENICILLIN POTASSIUM SALT G BBP is used at the beginning of treatment of severe infections caused by penicillin-sensitive pathogens (benzylpenicillin procaine may be continued at a later date). It is the drug of first choice for pneumonia and other infections caused by pneumococci (except enterococci), for pneumococcal meningitis (in combination with sulfonamides), infections caused by pyogenic streptococci, sensitive staphylococcus aureus, gonococci and meningococci (in combination with sulfonamides), and for the treatment of anthrax (splenic abscess), diphtheria, syphilis, listeriosis, actinomycosis. It is effective in infections caused by clostridia and corynebacteria and in the treatment of other infections caused by penicillin-sensitive organisms. Megadoses of benzylpenicillin are indicated in the treatment of subacute bacterial endocarditis (inflammation of the inner lining of the heart caused by bacteria) and bacterial meningitis (inflammation of the meninges), provided that tests demonstrate good sensitivity. Penicillin G is very effective in treating various stages of syphilis, including in patients with HIV and syphilis.

Treatment of hepatotoxic poisoning type 1 (poisoning with amanita muscaria verde and 27 other types of mushrooms containing amatoxins).

2. What you need to know before you start using PENICILLIN G POTASSIUM SALT BBP Do not use PENICILLIN G POTASSIUM SALT BBP

- if you are allergic to penicillins and cephalosporins or any of the other ingredients of this medicine (listed in section 6).

Caution is required when administering to people with a history of:

- allergy
- bronchial asthma,
- hay fever,
- urticaria.

When administering megadoses of benzylpenicillin, potassium salt, it is necessary to take into account a significant intake of potassium in the body, so megadoses should not be administered in the following cases:

- systemic neurological diseases,
- hyperkalemia (increased levels of potassium in the blood) and conditions that cause it.

Megadoses should be administered with extreme caution to children younger than 6 weeks of age and to persons over 60 years of age with impaired renal tubular function.

The administration of benzylpenicillin, potassium salt, is not contraindicated during pregnancy, puerperium, lactation or in patients with renal impairment (unless megadoses are administered).

Warnings and Precautions

Talk to your doctor, pharmacist, or nurse before using PENICILLIN G POTASSIUM SALT BBP.

When preparing the solution, it is necessary to avoid contact of the benzylpenicillin potassium salt solution with the skin or mucous membranes due to the high risk of hypersensitivity. For this reason, the air aspirated into the syringe should not be expelled into the air before administration, but always back into the empty vial. In case of anaphylactic shock (sudden allergic reaction) after administration of benzylpenicillin, potassium

In addition to salt, circulatory insufficiency and possible respiratory disorders should be controlled with adrenaline, noradrenaline, hydrocortisone, antihistamines and calcium. Principles are followed to manage these reactions.

Other Medications and PENICILLIN G POTASSIUM SALT BBP

tell your doctor or pharmacist if you are taking, have recently taken, or might need to take any other medications.

When administered simultaneously with bacteriostatic antibiotics (tetracyclines, chloramphenicol, erythromycin), there is a mutual reduction in effect. Benzylpenicillin potassium salt reduces the effectiveness of oral medications used to reduce blood clotting. Chlorpromazine (a medication for the treatment of psychosis) reduces the effectiveness of benzylpenicillin, a potassium salt. Concomitant administration of probenecid (a drug used to treat gout) causes a mutual increase in plasma levels. The level of penicillin in the blood increases with the simultaneous application of salicylates, aminophenazone (analgesics and fever reducers) and vitamin C. In infusion solutions, benzylpenicillin is incompatible with metaraminol, thiopental, amobarbital, ascorbic acid, promethazine, oxytetracycline, tetracycline, vancomycin, chloramphenicol and sulfadiazine. Benzylpenicillin, a potassium salt, increases the hypercaloremic efficacy (increased blood potassium levels) of other substances, causing false-positive results on tests for the presence of protein and sugar in the urine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you might be pregnant, or intend to become pregnant, talk to your doctor or pharmacist before using this medicine.

Long-term experience with the administration of benzylpenicillin, a potassium salt, has confirmed its safety for the fetus. In normal doses, the drug can be used during pregnancy.

Penicillin is excreted in breast milk and can cause hypersensitivity and allergic reactions. Therefore, breastfeeding should be discontinued during penicillin administration.

Driving and operating machinery

The influence of PENICILLIN G POTASSIUM SALT BBP on the ability to drive and use machines is null or negligible.

PENICILLIN POTASSIUM SALT G BBP contains 1.68 mmol (65.7 mg) of potassium per million dose units. It should be considered in patients with reduced renal function or in patients on a potassium-controlled diet.

3. How to use PENICILLIN G POTASSIUM SALT BBP

Follow the instructions for this medication as directed by your doctor or pharmacist exactly. If you are not sure, talk to your doctor or pharmacist.

Pharmacokinetic data show that benzylpenicillin, potassium salt, should be administered every four or at most every six hours, so the drug is only suitable for treatment in hospitalized patients. The dose depends on the type and location of the infectious process, the sensitivity of the etiologic agent, and the age of the patient. In the treatment of common infections, 25,000 – 100,000 IU/kg/day are administered intramuscularly or intravenously, divided into 4 doses.

- 6 partial doses. Typical daily doses are:

adults 800,000 to 2,400,000 IU

These doses are given for at least 3 days after the temperature has dropped and the clinical signs of the disease have disappeared. To complete the treatment of streptococcal infection, an injection of Pendepon or PENDEPON COMPOSITUM (benzathine benzylpenicillin, procaine benzylpenicillin) is required. Megadoses, i.e. from 15-30-60 to a maximum of 80 million IU per day, are used in the treatment of subacute bacterial endocarditis (bacterial inflammation of the inner lining of the heart) and bacterial meningitis. When megadoses are administered, a single dose should not exceed 10 million units and should be administered by intravenous infusion over at least one hour. For doses greater than 5 million units, renal function should be monitored no later than the second day of treatment. With a daily dose greater than 20 million units, the onset of neurotoxic reactions, which occur when the penicillin level exceeds 12 IU/ml of cerebrospinal fluid, should be expected. With further dose increases, penicillin levels in the blood and cerebrospinal fluid should also be monitored. When giving megadoses of benzylpenicillin, potassium salt, it is necessary to monitor the level of potassium in the blood. Therefore, this type of treatment can only be carried out in facilities where continuous monitoring is possible.

When administered topically (medication instillation and sinus irrigation), penicillin should always be administered concurrently by injection or oral administration.

In ophthalmology, for the treatment of infections caused by sensitive microbes, 200,000 IU dissolved in 1 ml of saline solution are administered subconjunctivally. This administration should be combined with injection. For the treatment of mushroom poisoning (hepatotoxic poisoning) it is necessary to administer megadoses of penicillin G, i.e. 300,000 to 2,000,000 IU per kg of body weight per day intravenously for three days to adults, children and pregnant women. It is advisable to combine treatment with the administration of silymarin at doses of 20 mg/kg body weight per day by intravenous infusion for 3 to 4 days.

Use in children and adolescents

The recommended dosage is:

children under 1 year of age 100,000 IU

Children from 1 year to 6 years 400,000 to 1,000,000 IU

Children over 6 years of age: 800,000 to 2,400,000 IU

These doses are given for at least 3 days after the temperature has dropped and the clinical signs of the disease have disappeared.

Children can also be given megadoses of 0.5 to 1.0 million IU per kg of body weight per day, but higher potassium intake should be considered. If signs of CNS irritation appear, application should be discontinued and an anticonvulsant may be administered. In the treatment of subacute bacterial endocarditis

(bacterial inflammation of the inner lining of the heart), megadoses of benzylpenicillin should be given for 4-6 weeks.

Method of administration:

Benzylpenicillin potassium salt solution is administered intravenously, intramuscularly, under the conjunctiva (subconjunctival - sci) and locally (sinus instillation and irrigation). When applied topically, penicillin should always be administered simultaneously by injection or through the oral cavity.

Preparation of the solution for injection:

Benzylpenicillin, potassium salt, is highly soluble even in a small volume of liquid (water for injection, isoosmotic solution of sodium chloride, 5% glucose solution) which is added to the vial in an amount calculated according to the desired concentration of solution. For megadose administration, the antibiotic is dissolved in 50-250 ml of water for injection.

If you forget to administer PENICILLIN G POTASSIUM BBP

Because this medication will be given to you under medical supervision, you are unlikely to miss a dose. However, if you think you have missed a dose, tell your doctor or pharmacist.

A missed dose will not be compensated by taking a double dose.

If you have any other questions about using this medication, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. The most serious and common side effect is allergic reactions, which are more common in people with allergic disposition.

Blood and lymphatic system disorders:

- indentation
- hemolytic anemia: a reduced number of red blood cells caused by their excessive breakdown,
- eosinophilia: an increase in the amount of a certain type of white blood cell in the blood and bone marrow,
- thrombocytopenia: reduction in the number of platelets in the blood (frequency unknown),
- Anemia: reduced levels of red blood cells in the blood (frequency unknown),
- Blood disorders.

Immune system disorders:

Severe allergic reactions

- The most serious manifestation is an anaphylactic reaction (sudden allergic reaction), which occurs

1-2 minutes after administration (sometimes within half an hour or later). After the initial symptoms listed below, a collapse can occur resulting in respiratory and heart failure, which can be fatal.

- Angioedema: Swelling of the skin, mucous membranes, and subcutaneous tissue, usually located on the face, mouth, or tongue (frequency unknown).

A severe allergic reaction may manifest as:

- rash, itchy skin,
- difficulty swallowing, breathing, or chest tightness,
- swelling of the eyelids, face, or lips
- swelling or redness of the tongue,
- fever
- joint pain,
- inflamed lymph nodes

Lupus eritematoso

Lupus erythematosus is a chronic inflammatory autoimmune disease that has very diverse manifestations and can affect the skin, joints, and often internal organs, such as the kidneys, lungs, heart, or brain.

Nervous system disorders:

- Metabolic encephalopathy: neurological disorders with seizures and loss of consciousness (frequency of occurrence unknown).

Mental disorders:

- headaches.

Nervous system disorders:

- symptoms of CNS irritation
- localized spasms of the muscles of the face or extremities, epileptiform seizures (seizures similar to

epilepsy) to generalized tonic-clonic seizures (tension and spasms of the muscles of the trunk and limbs) or even coma.

Gastrointestinal disorders:

- nausea, vomiting,
- Diarrhea: A rare side effect (may affect less than 1 in 1,000 people).
- Most often, after megadoses of benzylpenicillin, there is temporary bitterness in the mouth, sometimes vomiting.

Hepatobiliary disorders:

- cholestatic jaundice,
- liver dysfunction

Skin and subcutaneous tissue disorders:

- A serious complication can be Lyell syndrome (a more severe form that causes excessive peeling of the skin on more than 30% of the body surface) or Stevens-Johnson syndrome (severe and extensive syndrome).

blistering rash and peeling skin, especially around the mouth, nose, eyes, and genitals).

- Skin reactions whose frequency is unknown:
    - Acute generalized exanthematous pustulosis (AGAF), with symptoms such as severe rashes

reactions to medicines with or without skin redness, fever, pustules (fluid-filled blisters),

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  - maculopapular rash (flat, red area on the skin),
  - morbilliform rash (a rash that looks like measles),
  - itching
  - erythema (inflammatory redness of the skin).

Kidney and urinary disorders:

- Renal dysfunction

General disorders and alterations at the site of administration:

- During the treatment of syphilis, the Jarisch-Herxheimer reaction occurs in about 50% of cases, which is

It manifests itself with fever, sweating, headaches, and even collapse. The cause is the release of endotoxins. In cardiovascular syphilis, this reaction can have a very serious course (primary atrophy of the optic nerve - weakening of the optic nerve, nerve deafness) and can even cause death.

Reporting Side Effects

If you experience side effects, consult your doctor, pharmacist or pharmacist.

nurse. This also applies to any side effects not listed in this leaflet. You can also report side effects directly through the national reporting system listed in the Appendix.

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

5. How to store PENICILLIN G POTASSIUM SALT BBP

Store at a temperature below 25°C in the original container to protect it from light and moisture. Keep this medication out of the sight and reach of children.

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

Do not dispose of medicines in drains or in the trash. Return unused medications to the pharmacy. These measures will help protect the environment.

6. Package Contents and Other Information

What does PENICILLIN POTASSIUM SALT G BBP contain?

Active ingredient: benzylpenicillin, potassium salt 1,000,000 IU or 5,000,000 IU in one vial. Excipient: none.

1 million units contains 65.7 mg (1.68 mmol) of potassium.

Product appearance and packaging contents

PENICILLIN POTASSIUM SALT G BBP is a white or almost white microcrystalline powder.

Colorless glass vial with edge, rubber stopper, aluminum capsule with removable plastic lid (flip off), box.

Package Size

1, 10, 50 vials containing 1,000,000 IU

1, 10, 50 vials of 5,000,000 IU. Only certain sizes of packaging may be on the market.

Marketing authorisation holder and manufacturer

Marketing authorisation holder

BB Pharma as, Durychova 101/66, 142 00 Prague 4 - Lhotka, Czech Republic

Maker

AtB Pharma, sro, Sklabinská 28, 036 01 Martin, Slovak Republic

AtB Pharma, s.r.o., 976 13 Slovenská Ľupča 970, República Eslovaca

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