Package leaflet: Information for the patient

Benzylpenicillin Sodium 600 mg powder for solution for injection / infusion
Benzylpenicillin Sodium 1200 mg powder for solution for injection / infusion
Benzylpenicillin Sodium

Read all of this leaflet carefully before you start being given 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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Benzylpenicillin Sodium is and what it is used for
2. What you need to know before you are given Benzylpenicillin Sodium
3. How Benzylpenicillin Sodium is given
4. Possible side effects
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1. What Benzylpenicillin Sodium is and what it is used for

Benzylpenicillin Sodium is an antibiotic. It contains the active substance called benzylpenicillin sodium. It belongs to a family of medicines called "penicillins". It works by killing certain bacteria which can cause infections in adults, adolescents, children, newborn infants and premature infants.

This medicine is used for the following bacterial infections:
- skin and wound infections
- diphtheria (serious bacterial infection that usually affects the mucous membranes of the nose and throat)
- lung inflammation
- pus accumulation in body cavities
- inflammation of the
  - inner lining of the heart
  - membrane which lines the abdomen cavity and covers the abdominal organs
  - meninges (membranes that cover and protect your brain and spine)
  - bone marrow
- brain abscesses
- certain infections of the genital tract caused by fusobacteria
- anthrax
- tetanus
- gas gangrene (bacterial infection that produces tissue gas in gangrene)
- an infection mainly spread by spoiled or perished food called listeriosis
- pasteurellosis, an infection that can be caught via contact with affected animals as through cat bites or scratches
- rat bite fever
- fusospirochaetosis, a specific infection caused by ulceration of the skin and mucous membranes
- actinomycosis also known as "lumpy jaw"
- complications of sexual transmitted infection called gonorrhoea and syphilis

- *Lyme borreliosis*, an infection caused by bacteria transmitted by tics

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

2. What you need to know before you are given Benzylpenicillin Sodium

You must not be given Benzylpenicillin Sodium if you
- are allergic to benzylpenicillin
- have had allergic reactions through treatment with penicillin, such as skin rash, itching, fever, shortness of breath, drop in blood pressure
  Do not use this medicine as there is a risk of life-threatening allergic shock.
- have had a severe immediate allergic reaction to other medicines to treat bacterial infections called beta-lactam antibiotics, such as cephalosporin, carbapenem, monobactam

Warnings and precautions
Talk to your doctor or pharmacist before you are given Benzylpenicillin Sodium and during treatment if you:
- have ever experienced signs of intolerance after using other antibiotics, such as cephalosporins
  Your doctor will decide whether this medicine may be used and a hypersensitivity test is recommended before starting treatment.
- are prone to allergic reactions (such as nettle-rash or hay fever) or asthma
  In such cases, there is an increased risk of allergic reactions.
- have a heart condition or severe electrolyte disorders, such as of sodium, calcium, potassium, chloride.
  Your doctor should monitor your intake of electrolytes, especially your potassium intake.
- have reduced liver or kidney function
  Your doctor may have to adjust your dose or dosing interval of Benzylpenicillin Sodium
- have epilepsy, accumulation of fluid in your brain or inflammation of meninges
  Your doctor will carefully monitor you, as you are at increased risk of seizures during therapy.
- have a glandular fever, called mononucleosis
  There is an increased risk of skin reactions.
- have a cancer of white blood cells, called acute lymphatic leukaemia
  There is an increased risk of skin reactions.
- have a fungal skin disease
  You are at increased risk of developing allergy-like reactions.
- are using medicines to inhibit blood clotting
  Monitoring of blood clotting is recommended and dose adjustment by the doctor of the orally-taking medicine to inhibit blood clotting if necessary.
- have diabetes
  The absorption of Benzylpenicillin Sodium may be delayed in patients with diabetes if administered into the muscle.
- have a sexually-transmitted disease and syphilis
  Your doctor will perform tests before starting and during treatment.
- are being treated for Lyme borreliosis or complications of syphilis
  A temporary reaction called “Jarisch-Herxheimer reaction” may often occur due to the germ- killing effect of Benzylpenicillin Sodium. Symptoms are sudden fever, chills, skin redness, headache, muscle and joint pain, tiredness and exhaustion. The symptoms may persist for several days. Contact your doctor for help relieving these symptoms.
- have severe, persistent diarrhoea during treatment with Benzylpenicillin Sodium
  This diarrhoea could be a result of a treatment-associated inflammation of the colon. Symptoms are bloody, mucous to watery diarrhoea; dull, diffuse to gassy stomach pain; fever or, occasionally, a constant and painful need to pass stools. Your doctor should immediately stop using this medicine and

initiate appropriate treatment.

- long-term treatment over several weeks
  Treatment with Benzylpenicillin Sodium can cause overgrowth of certain non-sensitive bacteria or yeast-like fungi. Therefore, tell your doctor if you develop diarrhoea, itchy skin rash or growth of yeast-like fungi on mucous membranes. Furthermore, your doctor will regularly carry out certain blood tests during prolonged treatment of more than 5 days.
- to undergo a laboratory test
  Treatment with Benzylpenicillin Sodium can influence the results. Therefore, inform your doctor before any laboratory test is performed about your treatment with this medicine

Severe local reactions may occur in infants upon administration into the muscle. Therefore, injection into a vein for this age group should be performed wherever possible.

Other medicines and Benzylpenicillin Sodium
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

In particular, tell your doctor if you are using any of the following medicines:

- probenecid: to treat gout
- indomethacin, phenylbutazone, acetylsalicylic acid and similar medicines to reduce fever, inflammation, rheumatic disorders and pain
- other medicines to treat bacterial infections
  Benzylpenicillin only act on certain bacteria. Therefore, this medicine should only be combined with other medicines to treat bacterial infections as decided by the doctor.
- digoxin: to treat heart weakness
- methotrexate: to treat severe joint inflammation, cancer and the skin disease psoriasis (skin disease that causes a rash with itchy, scaly patches).
  Use of methotrexate together with Benzylpenicillin Sodium must be avoided wherever possible. If this cannot be avoided, reduction of methotrexate dose and monitoring of methotrexate blood level by the doctor is recommended. This includes monitoring for possible side effects of methotrexate.
- medicines taken orally to inhibit blood coagulation, such as acenocoumarol, warfarin
  If combined use is required, suitable blood-clotting parameters should be carefully monitored during and after stopping treatment with this medicine. A dose adjustment of the medicine to inhibit blood coagulation may be necessary.

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 you are given this medicine.

- **Pregnancy**
  Use of Benzylpenicillin Sodium is possible throughout pregnancy if the doctor assesses it is necessary.

- **Breast-feeding**
  Benzylpenicillin passes into breast milk in small amounts. Although no side effects have been reported in breast-fed infants to date, the possibility must be considered. Inform your doctor immediately if diarrhoea, candida yeast fungal infection or rash occur in the child.
  In babies also fed on baby food, mothers should express and discard breast milk during treatment with this medicine. Breast-feeding can be started again 24 hours after the end of treatment.

Driving and using machines
This medicine has no influence on the ability to concentrate and react. Serious side effects, like severe allergic reactions, this medicine can reduce the ability to react. Do not drive or use machines if you get serious side effects.

Benzylpenicillin Sodium contains sodium
This medicine contains 1.68 mmol sodium (main component of cooking/table salt) in each 600 mg.This is equivalent to 2.0% of the recommended maximum daily dietary intake of sodium for an adult.

Benzylpenicillin Sodium 600 mg powder for solution for injection / infusion
This medicine contains 39 mg sodium per vial, equivalent to 2.0 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Benzylpenicillin Sodium 1200 mg powder for solution for injection / infusion
This medicine contains 77 mg sodium per vial, equivalent to 3.9 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

3. How Benzylpenicillin Sodium is given

This medicine is usually administered by a doctor, who determines the method of use, dose and the dosing interval. Check with your doctor if you are not sure.

The usual recommended dose is:

- **adults and adolescents from 12 years**
  The usual daily dose is 600-3000 mg/day divided into 4 to 6 doses.
  In case of severe infection, the daily dose can be increased to 6-24 g/day.
- **children from 1 month up to their 12th birthday**
  The usual daily dose is 18-60 mg/kg/day per kilogram body weight divided into 4 to 6 doses. In case of severe infection, the daily dose can be increased to 60-600 mg/kg/day per kilogram body weight.
- **new-born babies from 2 weeks up to 1 month**
  The usual daily dose is 18-60 mg/kg/day per kilogram body weight divided into 3 to 4 doses. In case of severe infection, the daily dose can be increased to 120-600 mg/kg/day per kilogram body weight.
- **premature and new-born babies up to 2 weeks**
  The usual daily dose is 18-60 mg/kg/day per kilogram body weight divided into 2 doses. In case of severe infection, the daily dose can be increased to 0.12-0.6 g/kg/day per kilogram body weight.

Patients over 65 years and patients with kidney or liver problems
The doctor will check the kidney and liver function before and regularly during treatment. Based on the results, the doctor adjusts the dose and dosing interval as needed.

Duration of use
The duration of use is decided by the doctor. It depends on the severity of the infection, the germ-killing effect and the patient's symptoms, which can last from a few days to several weeks.

Method of use
Benzylpenicillin Sodium is usually administered by a doctor.

This medicine can be injected into a muscle or a vein. Administration into a vein can be given as an injection using a syringe or as a short infusion, generally lasting between 30 and 60 minutes.

If you are given more Benzylpenicillin Sodium than you should
Inform your doctor if you think you have been given too much. Overdose symptoms are increased excitability of nerves and muscles or susceptibility to fits in the brain.

If you forget to use Benzylpenicillin Sodium

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.

Severe allergic reactions (anaphylactic reactions or angioedema). If you have any of the side effects listed below, stop taking this medicine and seek urgent medical advice:

- 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

Side effects may occur with following frequencies:
Common: may affect up to 1 in 10 people
- effect on laboratory tests

Uncommon: may affect up to 1 in 100 people
- allergic reactions
- nettle-rash
- severe allergic reactions affecting the whole body or which causes difficulty in breathing, such as asthma, skin bleeding, stomach and bowel disorders
- severe skin reactions, such as:
  - skin rash with fever and blisters called erythema multiforme
  - large scaly skin inflammation called exfoliative dermatitis
- fever
- joint pain
- inflammation of the mouth lining
- tongue inflammation, black hairy tongue
- nausea, vomiting

Rare: may affect up to 1 in 1,000 people
- electrolyte disturbances due to rapid infusion of high doses
- nerve disorders
  Convulsive reactions may occur upon infusion of high doses. This should be particularly considered in patients with severely reduced kidney function, epilepsy, inflammation of meninges or accumulation of fluid in the brain. This also applies to patients where a machine temporarily takes over the function of the heart and lungs during surgery.
- diarrhoea
  If diarrhoea occurs, the possibility of colon inflammation should be considered. See section 2 “Warnings and precautions”.
- kidney disease
- abnormal presence of the protein albumin or blood in the urine
- sediment in the urine called cylindruria
- reduced urine output or failure to excrete urine
  This mostly clears up within 48 hours after stopping treatment.
- severe local reactions during administration into a muscle in infants

Very rare: may affect up to 1 in 10,000 people
- increased number of the white blood cells known as eosinophils
- reduced number of white blood cells (such as neutrophilic granulocytes, granulocytes), haemolytic

anaemia (reduced blood levels of red blood cells) or all of them
- blood-clotting disorders

Not known: frequency cannot be estimated from the available data
- AGEP – acute generalised 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 and mucosa and subcutaneous tissue, generally located on the face, mouth, or tongue)
- prolongation of the bleeding time and average time required in tests for blood to clot
- thrombocytopenia (reduced blood levels of platelets)
- a hypersensitivity reaction to proteins in the blood, called serum sickness, with symptoms of fever, lymph node swelling, local redness at the injection site, itching
- Jarisch-Herxheimer reaction, characterised by sudden fever, chills, skin redness, headache, muscle and joint pain, tiredness and/or exhaustion
- metabolic encephalopathy (neurological disorders with convulsions and loss of consciousness)
- liver inflammation
- reduced bile flow in the gallbladder
- skin disease with blisters called pemphigoid

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 HPRA Pharmacovigilance Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Benzylpenicillin Sodium

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 medicinal product does not require any special storage conditions.

Chemical and physical in-use stability of the reconstituted and diluted product is concentration and temperature dependent. The following in-use storage times have been demonstrated:

	2°C to 8°C	**below 25°C**
300-546 mg/ml (this range includes the recommended concentration for IM injection)	6 hours	1 hour

60 mg/ml (the recommended concentration for IV injection/infusion)	8 hours	1 hour

From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of the user.

6. Contents of the pack and other information

What Benzylpenicillin Sodium contains
The active substance is benzylpenicillin as sodium salt.

Benzylpenicillin Sodium 600 mg powder for solution for injection / infusion:
Each vial contains 600 mg benzylpenicillin sodium.

Benzylpenicillin Sodium 1200 mg powder for solution for injection / infusion:
Each vial contains 1200 mg benzylpenicillin sodium.

What Benzylpenicillin Sodium looks like and contents of the pack
Benzylpenicillin Sodium is a white or almost white crystalline powder. It comes in a glass vial with bromobutyl rubber stopper and sealed with tear-off caps or flip-off caps in aluminium with plastic top.

Pack sizes:
Benzylpenicillin Sodium 600 mg powder for solution for injection / infusion:10 vials (with nominal volume of 15 ml)

Benzylpenicillin Sodium 1200 mg powder for solution for injection / infusion: 10 vials (with nominal volume of 15 ml)

Not all pack-sizes may be marketed

Marketing Authorisation Holder

Fresenius Kabi Deutschland GmbH
Else-Kroener-Strasse 1
61352 Bad Homburg v.d.Hoehe
Germany

Manufacturer
Labesfal - Laboratórios Almiro, S.A.
Zona Industrial do Lagedo,
Santiago de Besteiros, 3465-157,
Portugal

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Penicillin G Kabi 1 Million I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung Penicillin G Kabi 2 Millionen I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung
Belgium	Penicilline G Kabi 1 000 000 IU poeder voor oplossing voor injectie/infusie Penicilline G Kabi 1 000 000 IU Poudre pour solution injectable/pour perfusion Penicilline G Kabi 1 000 000 IU Pulver zur Herstellung einer Injektions- Infusionslösung Penicilline G Kabi 2 000 000 IU poeder voor oplossing voor injectie/infusie Penicilline G Kabi 2 000 000 IU Poudre pour solution injectable/pour perfusion Penicilline G Kabi 2 000 000 IU Pulver zur Herstellung einer Injektions-/Infusionslösung
Czechia	Benzylpenicillin sodium Kabi
Denmark	Benzylpenicillin Fresenius Kabi
Estonia	Benzylpenicillin Sodium Kabi
Finland	Benzylpenicillin Fresenius Kabi 0,6 g, 1,2 g, 3 g, 6 g injektio-/infuusiokuiva-aine, liuosta varten
Germany	Penicillin G Kabi 1 Million I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung Penicillin G Kabi 2 Millionen I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung
Ireland	Benzylpenicillin sodium 600 mg powder for solution for injection/infusion Benzylpenicillin sodium 1200 mg powder for solution for injection/infusion
Latvia	Benzylpenicillin Sodium Kabi 1 000 000 SV pulveris injekciju vai infūziju šlīduma pagatavošanai Benzylpenicillin Sodium Kabi 2 000 000 SV pulveris injekciju vai infūziju šlīduma pagatavošanai

Lithuania	Benzylpenicillin Sodium Kabi 1 000 000 TV milteliai injekciniam ar infuziniam tirpalui Benzylpenicillin Sodium Kabi 2 000 000 TV milteliai injekciniam ar infuziniam tirpalui
Luxembourg	Penicillin G Kabi 1 Million I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung Penicillin G Kabi 2 Millionen I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung
Netherlands	Penicilline G Kabi 1 000 000 IU poeder voor oplossing voor injectie/infusie Penicilline G Kabi 2 000 000 IU poeder voor oplossing voor injectie/infusie
Norway	Benzylpenicillin Fresenius Kabi
Romania	Penicilină G sodică Fresenius Kabi 1000000 UI pulbere pentru soluție injectabilă/perfuzabilă
Slovakia	Benzylpenicillin sodium Kabi 1 MIU Benzylpenicillin sodium Kabi 5 MIU Benzylpenicillin sodium Kabi 10 MIU
Slovenia	Penicilin G Kabi 1 000 000 i.e. (1 milijon i.e.) prašek za raztopino za injiciranje/infundiranje Penicilin G Kabi 2 000 000 i.e. (2 milijona i.e.) prašek za raztopino za injiciranje/infundiranje
Sweden	Benzylpenicillin Fresenius Kabi

This leaflet was last revised in July 2025..

The following information is intended for healthcare professionals only:

Incompatibilities

The contents of the vial should only be used in a solution with water for injections, 5% (50 mg/mL) glucose solution or 0.9% (9 mg/mL) sodium chloride, in order to avoid incompatibilities.

In order to avoid undesirable chemical reactions or undesirable effects, the already dissolved vials should not be mixed with other mixed injections or infusions (e.g. Ringer's lactate solution).
Oxidising and reducing substances, alcohol, glycerol, macrogols and other hydroxy compounds can

inactivate benzylpenicillin.
Benzylpenicillin solutions are most stable in the pH range 6 – 7 (optimum pH 6.8). Benzylpenicillin is incompatible in solution with the following:

- cimetidine
- cytarabine
- chlorpromazine hydrochloride
- dopamine hydrochloride
- heparin
- hydroxyzine hydrochloride
- lactate
- lincomycin hydrochloride
- metaraminol
- sodium hydrogen carbonate
- oxytetracycline
- pentobarbital
- tetracycline hydrochloride
- thiopental sodium
- vancomycin

Benzylpenicillin is not compatible with vitamin B complex and ascorbic acid in mixed solutions.

Special precautions for disposal and other handling
In order to avoid hypersensitivity reactions caused by degradation of product, it is recommended to use the injection or infusion solution immediately after preparation. The administration should at least take place within the maximum recommended in-use shelf life (see section 5).

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Preparation of a solution for IV injection or infusion:
A solution for intravenous use can be prepared with the following solvents:

- water for injections (WFI)
- 5% (50 mg/mL) glucose solution
- 0.9% (9 mg/mL) sodium chloride solution

The recommended concentration for intravenous use is 60 mg/ml.

An isotonic solution is obtained when using WFI as solvent (osmolarity of 60 mg/ml in WFI is 337 mOsmol/l). It should be taken in account that more concentrated solutions and solutions in 5% (50 mg/mL) glucose or 0.9% (9 mg/mL) sodium chloride are hypertonic and that the use of 0.9% sodium chloride leads to an additional supply of electrolytes.

For **Benzylpenicillin Sodium 600 mg and 1200 mg** powder for solution for injection / infusion a two-step preparation is required, i.e. reconstitution in the original vial followed by dilution of the concentrated solution in another container.

The reconstitution and dilution instructions in the table underneath result in an IV injection / infusion of 60 mg/ml .

Reconstitution and dilution instructions for intravenous injection / infusion				
	Reconstitution step		***Dilution step***	
1 vial	*Recommended volume of solvent to be added for reconstitution*	*Resulting (concentrate for) solution for IV injection / infusion*	*Dilution until 6000 mg/100 ml (or 60 mg/ml)*	*Resulting solution for injection / infusion*
Benzylpenicillin Sodium **600 mg** powder for solution for injection / infusion *(contains ± 0.6 gram powder)*	4.6 ml	**concentrate to be diluted before use** 5 ml = 600 mg (120 mg/ml)	1 volume concentrate + 1 volume diluent e.g. add 5 ml concentrate to 5 ml diluent	**ready for use** 10 ml = 600 mg (60 mg/ml)
Benzylpenicillin Sodium **1200 mg** powder for solution for injection / infusion *(contains ± 1.2 gram powder)*	9.2 ml	**concentrate to be diluted before use** 10 ml = 1200 mg (120 mg/ml)	1 volume concentrate + 1 volume diluent e.g. add 10 ml concentrate to 10 ml diluent	**ready for use** 20 ml = 1200 mg (60 mg/ml)

Preparation of a solution for IM injection:

A solution for intramuscular use can be prepared with the following solvent:

- water for injections (WFI)

Due to the concentrated nature of a solution for intramuscular injection the recommended solvent is WFI in order to keep to tonicity as low as possible (any solution exceeding 60 mg/ml is hypertonic).

The maximum volume for intramuscular administration is 5 ml per injection site and the maximum intramuscular dose is 6000 mg. Higher doses can be given as intravenous infusion (see section 3). Instructions for the one-step reconstitution in the original vial in the minimum amounts of solvent is described in the table underneath. Further dilution is possible, but depends on the combination of intended dose and maximum injection volume of 5 ml per injection site.

Reconstitution instructions for intramuscular injection		
1 Vial	*Recommended volume of solvent to be added for reconstitution*	*Resulting solution for intramuscular injection* **(maximum 5 ml per injection site)**
Benzylpenicillin Sodium > **600 mg** powder for solution for injection / infusion *(contains ± 0.6 gram powder)*	0.6 - 1 ml	
	e.g. 0.6 ml	1.1 ml = 600 mg (545 mg/ml)
	e.g. 1 ml	1.5 ml = 600 mg (400 mg/ml)
Benzylpenicillin Sodium **1200 mg** powder for solution for injection / infusion *(contains ± 1.2 gram powder)*	1.2-2 ml	
	e.g. 1.2 ml	2.2 ml = 1200 mg (545 mg/ml)
	e.g. 2 ml	3 ml = 1200 mg (400 mg/ml)

Notes on intramuscular injection:

Up to a maximum of 6 g Benzylpenicillin Sodium, dissolved in 6 to 10 mL water for injection, is administered up to twice daily as a deep intramuscular injection into the upper, outer quadrant of the gluteus maximus or Hochstetter's ventrogluteal field.
5 mL per injection site should be regarded as the upper limit of tolerability. Repeated injections should be given on alternate sides. Higher doses can be given as an intravenous infusion.
Severe local reactions may occur with intramuscular administration, especially in infants. If possible, intravenous therapy should be performed.

The reconstituted solution should be clear, colorless to slightly yellow solution and practically free from visible particles.

Caution: Cerebral seizures may occur if the infusion is too rapid.