

## 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 3000 mg powder for solution for injection / infusion**  
**Benzylpenicillin sodium 6000 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.
- 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
5. How to store Benzylpenicillin sodium
6. Contents of the pack and other information

### 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 membrane 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 ticks.

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 oral medicine taken 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 this 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 giving you this medicine and initiate appropriate treatment
- have 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

- have 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 (blood thinning medicine), 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, can reduce the ability to react. Do not drive or use machines if you get serious side effects.

### **Benzylpenicillin sodium contains sodium**

[600 mg powder for solution for injection / infusion]

This medicine contains 38.7 mg sodium per vial equivalent to 1.9 % of the WHO recommended maximum

daily intake of sodium for an adult.

[1200 mg powder for solution for injection / infusion]

This medicine contains 77.4 mg sodium per vial equivalent to 3.9 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

[3000 mg powder for solution for injection / infusion]

This medicine contains 193.5 mg sodium per vial equivalent to 9.7 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

[6000 mg powder for solution for injection / infusion]

This medicine contains 387 mg sodium per vial equivalent to 19.3 % 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 6000-24000 mg/day.
- **children from 1 month up to 12 years of age**  
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 120-600 mg/kg/day per kilogram body weight.

#### **Use in 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 miss a dose of 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.

**Contact your doctor immediately if you get any of the following side effects:**

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface - toxic epidermal necrolysis),
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)),
- a red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis).

**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 (feeling sick), vomiting (being sick)

**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

- 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 the national reporting system HPRA Pharmacovigilance, Website: [www.hpra.ie](http://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.

This medicine does not require any special storage conditions.

For single use only. Discard any unused solution.

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.

### **Intramuscular use**

*After reconstitution with water for injection in a final concentration 400-545 mg/mL*

Chemical and physical in-use stability has been demonstrated for:

**Final concentration 400mg/mL or 545 mg/mL:**

- 4 hours at 25°C under artificial light
- 24 hours at 2-8°C protected from light

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

**Intravenous injection/infusion**

After reconstitution and dilution with water for injection, sodium chloride 9 mg/mL (0.9%) or glucose 5 % in a final concentration 60 mg/mL

- 2 hours at 25°C under artificial light
- 12 hours at 2-8°C protected from light

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.

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 sodium contains**

The active substance is benzylpenicillin as sodium salt.

**Benzylpenicillin sodium 600 mg**

Each vial contains 600 mg (equivalent to approximately 1000 000 IU) benzylpenicillin sodium.

**Benzylpenicillin sodium 1200 mg**

Each vial contains 1200 mg (equivalent to approximately 2 000 000 IU) benzylpenicillin sodium.

**Benzylpenicillin sodium 3000 mg**

Each vial contains 3000 mg (equivalent to approximately 5 000 000 IU) benzylpenicillin sodium.

**Benzylpenicillin sodium 6000 mg**

Each vial contains 6000 mg (equivalent to approximately 10 000 000 IU) benzylpenicillin sodium.

**What Benzylpenicillin sodium looks like and contents of the pack**

White or almost white, crystalline powder for solution for injection/infusion.

Benzylpenicillin sodium 600mg, 1200 mg, 3000 mg powder for solution for injection/infusion [powder for injection/infusion]:

20 mL Type III clear glass colourless vial sealed with chlorobutyl rubber stoppers and aluminum caps, with polypropylene flip-off covers.

Benzylpenicillin sodium 6000 mg powder for solution for injection/infusion [powder for injection/infusion]:

50 mL Type III clear glass colourless vial sealed with chlorobutyl rubber stoppers and aluminum caps, with polypropylene flip-off covers.

This medicinal product is supplied in cartons of 1 or 10 vials.

Not all pack-sizes may be marketed

**Marketing Authorisation Holder**

Noridem Enterprises Ltd.  
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Nicosia 1065, Cyprus

**Manufacturer**

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

Ireland	Benzylpenicillin sodium 600 mg powder for solution for injection/infusion Benzylpenicillin sodium 1200 mg powder for solution for injection/infusion Benzylpenicillin sodium 3000 mg powder for solution for injection/infusion Benzylpenicillin sodium 6000 mg powder for solution for injection/infusion
Austria	Benzylpenicillin Natrium Noridem 1 Mega IE Pulver zur Herstellung einer Injektions-/Infusionslösung Benzylpenicillin Natrium Noridem 2 Mega IE Pulver zur Herstellung einer Injektions-/Infusionslösung Benzylpenicillin Natrium Noridem 5 Mega IE Pulver zur Herstellung einer Injektions-/Infusionslösung Benzylpenicillin Natrium Noridem 10 Mega IE Pulver zur Herstellung einer Injektions-/Infusionslösung
Germany	Benzylpenicillin- Natrium Noridem 1 Million I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung Benzylpenicillin- Natrium Noridem 2 Millionen I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung Benzylpenicillin- Natrium Noridem 5 Millionen I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung Benzylpenicillin- Natrium Noridem 10 Millionen I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung
Czech Republic	Benzylpenicillin sodium Noridem Benzylpenicillin sodium Noridem Benzylpenicillin sodium Noridem Benzylpenicillin sodium Noridem
Spain	Bencilpenicilina sodica Noridem 1 MIU polvo para solución inyectable y para perfusión Bencilpenicilina sodica Noridem 2 MIU polvo para solución inyectable y para perfusión Bencilpenicilina sodica Noridem 5 MIU polvo para solución inyectable y para perfusión Bencilpenicilina sodica Noridem 10 MIU polvo para solución inyectable y para perfusión
Finland	Benzylpenicillin Noridem 0,6 g injektio-/infuusiokuiva-aine liuosta varten

	Benzylpenicillin Noridem 1,2 g injektio-/infuusiokuiva-aine liuosta varten
	Benzylpenicillin Noridem 3 g injektio-/infuusiokuiva-aine liuosta varten
	Benzylpenicillin Noridem 6 g injektio-/infuusiokuiva-aine liuosta varten
Croatia	Benzilpenicilinnatrij Noridem 1 MIU prašak za otopinu za injekciju / infuziju
	Benzilpenicilinnatrij Noridem 2 MIU prašak za otopinu za injekciju / infuziju
	Benzilpenicilinnatrij Noridem 5 MIU prašak za otopinu za injekciju / infuziju
	Benzilpenicilinnatrij Noridem 10 MIU prašak za otopinu za injekciju / infuziju
Netherlands	Natriumbenzylpenicilline Noridem 1 000 000 IE poeder voor oplossing voor injectie/infusie
	Natriumbenzylpenicilline Noridem 2 000 000 IE poeder voor oplossing voor injectie/infusie
	Natriumbenzylpenicilline Noridem 5 000 000 IE poeder voor oplossing voor injectie/infusie
	Natriumbenzylpenicilline Noridem 10 000 000 IE poeder voor oplossing voor injectie/infusie
Norway	Benzylpenicillin Noridem
	Benzylpenicillin Noridem
	Benzylpenicillin Noridem
	Benzylpenicillin Noridem
Poland	Benzylpenicylina sodowa Noridem
	Benzylpenicylina sodowa Noridem
	Benzylpenicylina sodowa Noridem
	Benzylpenicylina sodowa Noridem
Portugal	Benzilpenicilina sódica Noridem
	Benzilpenicilina sódica Noridem
	Benzilpenicilina sódica Noridem
	Benzilpenicilina sódica Noridem
Greece	NEOVALEN
Sweden	Benzylpenicillin Noridem
	Benzylpenicillin Noridem
	Benzylpenicillin Noridem
	Benzylpenicillin Noridem
Slovakia	Benzylpenicillin sodium Noridem 1 MIU prášok na injekčný/infúzny roztok
	Benzylpenicillin sodium Noridem 2 MIU prášok na injekčný/infúzny roztok
	Benzylpenicillin sodium Noridem 5 MIU prášok na injekčný/infúzny roztok
	Benzylpenicillin sodium Noridem 10 MIU prášok na injekčný/infúzny roztok
Cyprus	NEOVALEN

**This leaflet was last revised in**

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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 (osmolality of 60 mg/ml in WFI is 337 mOsm/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.

Strength	Resulting solution for IV injection/ infusion	Reconstituted and diluted solution with WFI	Reconstituted and diluted solution with NaCl 0.9%	Reconstituted and diluted solution with Dextrose 5%
		Osmolality (mOsm/kg)		

<b>600 mg</b>	60 mg/ml	328	602	629
<b>1200 mg</b>	60 mg/ml	337	614	643
<b>3000 mg</b>	60 mg/ml	334	600	634
<b>6000 mg</b>	60 mg/ml	333	599	634

Benzylpenicillin sodium 3000 mg, 6000mg 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.

<b>Reconstitution and dilution instructions for intravenous injection / infusion</b>				
	<b>Reconstitution step</b>		<b>Dilution step</b>	
<i>1 vial</i>	<i>Recommended volume of solvent to be added for reconstitution</i>	<i>Resulting (concentrate for) solution for injection / infusion</i>	<i>Dilution until 6000 mg/100 mL (or 60 mg/ml)</i>	<i>Resulting solution for injection / infusion</i>
Benzylpenicillin sodium <b>600 mg</b> powder for solution for injection/ infusion	9.6 mL	<b>ready for use</b>  10 mL = 600 mg (60 mg/mL)		
Benzylpenicillin sodium <b>1200 mg</b> powder for solution for injection/ infusion	19.2 mL	<b>ready for use</b>  20 mL = 1200 mg (60 mg/mL)		
Benzylpenicillin sodium <b>3000 mg</b> powder for solution for injection/ infusion	7.9 mL	<b>concentrate to be diluted before use</b>  10 mL = 3000 mg (300 mg/mL)	1 volume concentrate + 4 volumes diluent  e.g. add 10 mL concentrate to 40 mL diluent	<b>ready for use</b>  50 mL = 3000 mg (60 mg/mL)
Benzylpenicillin sodium <b>6000 mg</b> powder for solution for injection/ infusion	15.8 mL	<b>concentrate to be diluted before use</b>  20 mL = 6000 mg (300 mg/mL)	1 volume concentrate + 4 volumes diluent  e.g. add 20 mL concentrate to 80 mL diluent	<b>ready for use</b>  100 mL = 6000 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.

<b>Reconstitution instructions for intramuscular injection</b>		
<i>1 vial</i>	Recommended volume of solvent to be added for reconstitution	Resulting solution for intramuscular injection <b>(maximum 5 mL per injection site)</b>
Benzylpenicillin sodium <b>600 mg</b> powder for solution for injection/ infusion	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 <b>1200 mg</b> powder for solution for injection/ infusion	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)
Benzylpenicillin sodium <b>3000 mg</b> powder for solution for injection/ infusion	3-5 mL	
	e.g. 3 mL	5.5 mL = 3000 mg (545 mg/mL)
	e.g. 5 mL	7.5 mL = 3000 mg (400 mg/mL)
Benzylpenicillin sodium <b>6000 mg</b> powder for solution for injection/ infusion	6-10 mL	
	e.g. 6 mL	11 mL = 6000 mg (545 mg/mL)
	e.g. 10 mL	15 mL = 6000 mg (400 mg/mL)

Notes on intramuscular injection:

Up to a maximum of 6000 mg 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 sites. 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 pale yellow solution and practically free from visible particles.

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