**Benzylpenicillin 500,000, 1,000,000, 5,000,000, 10,000,000 IU,**

**What is Benzylpenicillin, and what is this medicine used for?**

Benzylpenicillin is a medicine used to treat infections caused by benzylpenicillin-sensitive bacteria. This medicine is used for the treatment of adults, adolescents, children, newborn infants, and premature infants.

Benzylpenicillin is used for the following bacterial infections:

* Skin and wound infections
* Diphtheria
* Pneumonia
* Accumulation of pus in body cavities
* Infections of the superficial layer of the skin that appear as a well-defined extensive redness called Erysipelas

• Inflammation of:

* The tissue inside the heart
* The membrane lining the abdominal cavity and covering the abdominal organs
* Meningitis (inflammation of the membranes surrounding the brain and spinal cord)
* The bone marrow
* Abscesses in the brain
* Certain inflammations of the genital organs
* Anthrax
* Tetanus

Gas gangrene

* An infection that primarily spreads through spoiled food called listeriosis
* Pasteurellosis, an infection that can be contracted through contact with infected animals, such as cat bites or scratches
* Rat-bite fever
* Fusospirochaetosis, a specific infection caused by sores on the skin and mucous membranes
* Actinomycosis, also known as 'lumpy jaw'
* Complications of sexually transmitted diseases called gonorrhea and syphilis
* Lyme borreliosis, 'Lyme disease,' an infection caused by a bacterium transmitted by ticks.

**When should you not use this medicine or use it with extra caution?**

When should you not use this medicine?

If you:

* Are allergic to benzylpenicillin
* Have experienced hypersensitivity reactions to penicillin treatment, such as skin rash, itching, fever, shortness of breath, or low blood pressure.
* Do not use Benzylpenicillin if there is a risk of life-threatening allergic shock.
* Have had a severe acute hypersensitivity reaction to other drugs that treat bacterial infections called beta-lactam antibiotics, such as cephalosporin, carbapenem, monobactam.
* When should you take extra caution with this medicine?
* Contact your doctor or pharmacist before using this medicine and during treatment if you:
* Have ever experienced symptoms of intolerance after using other antibiotics, such as cephalosporin. Your doctor will decide whether you can use benzylpenicillin, and a hypersensitivity test is recommended before treatment.
* Are sensitive to allergic reactions (e.g., hives or hay fever) or have asthma. In this case, there is an increased risk of hypersensitivity reactions.
* Have or have had a heart condition or a severe electrolyte imbalance, such as sodium, calcium, potassium, chloride. Your doctor should monitor your electrolyte intake, especially your potassium intake.
* Have impaired liver or kidney function. Your doctor may need to adjust your dosage or the time between two doses.
* Have epilepsy, brain edema, or meningitis. Your doctor will closely monitor you as you are at an increased risk of having a seizure during treatment.
* Have infectious mononucleosis (Pfeiffer's disease). There is an increased risk of skin reactions.
* Have cancer of white blood cells, called acute lymphoblastic leukemia. There is an increased risk of skin reactions.
* Has a fungal skin disease.
* You are at an increased risk of developing allergy-like reactions.
* Takes medications to inhibit blood clotting.
* Control of blood clotting is recommended, and if necessary, the doctor may adjust the dose of the orally administered medicine to inhibit blood clotting.
* Has diabetes.
* The absorption of Benzylpenicillin may be delayed in patients with diabetes when administered intramuscularly.
* Has a sexually transmitted disease and syphilis.
* Your doctor will conduct tests before and during the treatment.
* Is being treated for Lyme borreliosis or complications of syphilis.
* A temporary reaction (the so-called Jarisch-Herxheimer reaction) often occurs due to the bactericidal effect of benzylpenicillin. Symptoms may include sudden fever, chills, skin redness, headache, muscle and joint pain, fatigue, and/or exhaustion. The symptoms may persist for several days. Contact your doctor so they can help alleviate these symptoms.
* Experiences severe, persistent diarrhea during treatment with this medicine.
* This may be due to treatment-related inflammation of the colon. Symptoms include bloody/mucous, watery diarrhea; dull, diffuse to colicky abdominal pain; fever, or, in some cases, constant and painful urge for bowel movements. Your doctor should immediately discontinue the use of Benzylpenicillin and start appropriate treatment.
* Is undergoing a prolonged treatment of several weeks.
* Treatment with Benzylpenicillin may cause excessive growth of certain non-sensitive bacteria or yeast-like fungi. Therefore, inform your doctor if you experience diarrhea, itchy skin rash, or mucous membrane growth caused by yeast-like fungi. Additionally, during prolonged treatment of more than 5 days, your doctor will regularly perform blood tests.
* Is undergoing a laboratory test.
* Treatment with this medicine may influence the results. Therefore, inform your doctor before undergoing a laboratory test about your treatment with this medicine.
* Severe local reactions may occur in infants after intramuscular administration. Therefore, whenever possible, injection in a vein should be performed in this age group.
* Are you using any other medicines?
* If you are using other medicines alongside benzylpenicillin, have done so recently, or are planning to use other medicines in the near future, please inform your doctor or pharmacist.
* It is particularly important to tell your doctor if you are using any of the following medicines:
* Probenecid: for the treatment of gout.
* Indomethacin, phenylbutazone, acetylsalicylic acid, and similar medicines to reduce fever, inflammation, rheumatic conditions, and pain.
* Other medicines to treat bacterial infections.
* Benzylpenicillin only works on certain bacteria. Therefore, Benzylpenicillin should only be combined with other medicines for the treatment of bacterial infections as determined by the doctor.
* Digoxin: to treat heart failure.
* Methotrexate: for the treatment of severe joint inflammation, cancer, and the skin disease psoriasis.
* Combined use of methotrexate and Benzylpenicillin should be avoided where possible. If simultaneous use cannot be avoided, it is recommended to reduce the dose of methotrexate and have the blood level of methotrexate monitored by the doctor. This includes monitoring for possible additional side effects of methotrexate.
* Oral anticoagulant medications, such as acenocoumarol, warfarin. If combined use is required, appropriate blood clotting parameters should be carefully monitored during and after discontinuation of treatment with benzylpenicillin. Dose adjustment of the anticoagulant medication may be necessary.

**Pregnancy and breastfeeding:** Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Please contact your doctor or pharmacist before using this medicine.

**Pregnancy:** The use of Benzylpenicillin is possible during pregnancy if the doctor deems it necessary. However, this medicine is not recommended for the treatment of syphilis during pregnancy.

**Breastfeeding:** Benzylpenicillin is excreted in small amounts in breast milk. Although no side effects have been reported in breastfed infants so far, the possibility should be considered. Inform your doctor immediately if diarrhea, candidiasis, or rash occurs in the child.

For infants who are also receiving formula, the mother should pump and discard the milk during treatment with this medicine. Breastfeeding can be resumed 24 hours after the end of treatment.

**Driving and using machines:** Generally, this medicine does not affect concentration and reaction ability. However, severe side effects, such as severe allergic reactions, may reduce reaction ability. Avoid driving or operating machinery if such severe side effects occur.

**Benzylpenicillin contains sodium:** This medicine contains 1.68 mmol of sodium (main component of table salt) per 1,000,000 IU. This corresponds to 0.1% of the recommended maximum daily intake of sodium for an adult.

[**500,000 IU powder for solution for injection/infusion]:** This medicine contains less than 1 mmol of sodium (23 mg) per vial, making it essentially 'sodium-free'.

**[1,000,000 IU powder for solution for injection/infusion]:** This medicine contains 38.6 mg of sodium per vial, equivalent to 1.9% of the WHO-recommended maximum daily intake of 2 g of sodium for an adult.

**[5,000,000 IU powder for solution for injection/infusion]:** This medicine contains 193 mg of sodium per vial, equivalent to 9.7% of the WHO-recommended maximum daily intake of 2 g of sodium for an adult.

**[10,000,000 IU powder for solution for injection/infusion]:** This medicine contains 386 mg of sodium per vial, equivalent to 19.3% of the WHO-recommended maximum daily intake of 2 g of sodium for an adult.

**How to use this medicine?**This medicine is usually administered by a doctor. Your doctor will determine the route of administration, dosage, and dosing interval. Consult your doctor if you are unsure.

**The usual recommended dose is:**

• **Adults and adolescents from 12 years old:** The usual daily dose is 1 to 5 million IU (international units), 0.6-3 g/day, 600-3000 mg/day, divided into 4 to 6 doses. In case of severe infection, the daily dose can be increased to 10 to 40 million IU, 6-24 g/day, 6000-24000 mg/day.

• **Children from 1 month to their 12th birthday:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 4 to 6 doses. In case of severe infection, the daily dose can be increased to 0.1 to 1 million IU per kilogram of body weight, 0.06-0.6 g/kg/day, 60-600 mg/kg/day.

• **Newborn infants from 2 weeks to 1 month old:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 3 to 4 doses. In case of severe infection, the daily dose can be increased to 0.2 to 1 million IU per kilogram of body weight, 0.12-0.6 g/kg/day, 120-600 mg/kg/day.

**• Premature and newborn infants up to 2 weeks old:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 2 doses. In case of severe infection, the daily dose can be increased to 0.2 to 1 million IU per kilogram of body weight, 0.12-0.6 g/kg/day, 120-600 mg/kg/day.

**Patients over 65 years old and patients with impaired kidney or liver function:** The doctor will check kidney and liver function prior to and regularly during treatment. Based on the results, the doctor may adjust the dosage and dosing interval if necessary.

**Duration of treatment and use:** The duration of treatment and use will be determined by the doctor. This depends on the severity of the infection, the bactericidal effect, and the patient's symptoms, which may last for several days to a few weeks.

**Method of administration:** This medicine is usually administered by a doctor.

This medicine can be administered into a muscle or a vein. Intravenous administration can be given as an injection (using a syringe) or as a short-term infusion, usually between 30 and 60 minutes.

**Have you received too much of this medicine:**Tell your doctor if you think you have received too much. Symptoms of overdose may include increased irritability of nerves and muscles or susceptibility to seizures in the brain.

**Have you forgotten to use this medicine?**Contact your doctor immediately.

**Possible side effects**:
Like all medicines, this medicine can have side effects, although not everyone gets them. Contact your doctor immediately if you experience any of the following side effects:

* Rash with blisters and skin peeling all over your body, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson Syndrome). Or a more severe form where your skin peels all over your body (more than 30% of the body's surface area - toxic epidermal necrolysis).
* Flu-like symptoms, such as rash, fever, swollen glands. Unusual blood test results may also be seen, including an increased number of white blood cells (eosinophilia) and liver enzymes in your blood (Drug Reaction with Eosinophilia and Systemic Symptoms - DRESS).
* A red, scaly rash with bumps under the skin and blisters (exanthemateuze pustulose).
* Severe allergic reactions (anaphylactic reactions or angioedema) that can occur as:
* Skin rash or itchy skin, breathing difficulties or tightness in the chest, swollen eyelids, face, or lips, swelling or redness of the tongue, fever, joint pain, swollen lymph nodes.
* Side effects can occur with the following frequencies:

**Common (affecting less than 1 in 10 users):**

 • Effect on laboratory tests.

**Uncommon (affecting less than 1 in 100 users):**

* Allergic reactions,
* Hives,
* Severe allergic reactions affecting the whole body or causing breathing difficulties, such as asthma, skin bleeding, stomach and intestinal 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 oral mucosa
* Tong inflammation, black hairy tongue
* Nausea, vomiting.

**Rare (occur in less than 1 in 1000 users):**

* Electrolyte disturbances can occur after rapid infusion of high doses.
* Nerve disorders
* Convulsive reactions can occur after infusion of high doses. This should be taken into account, especially in patients with severe renal insufficiency, epilepsy, meningitis, or cerebral edema. This also applies to patients in whom a machine temporarily takes over the function of the heart and lungs during surgery.
* Diarrhea

If diarrhea occurs during treatment, the possibility of colitis should be considered. See section 'When should you be extra cautious with this medicine?'.

* Kidney disease
* Abnormal presence of the protein albumin or blood in the urine
* Sediment in the urine called cylindruria
* Reduced urine production or non-excretion of urine. This usually disappears within 48 hours after stopping treatment.
* Severe local reactions during administration into a muscle in infants.

**very rare (occur in less than 1 in 10,000 users):**

* Increased number of white blood cells known as eosinophils
* Decreased number of white blood cells (such as neutrophil granulocytes, granulocytes), hemolytic anemia (reduced blood levels of red blood cells), or both.
* Blood clotting disorders.

**How to store this medicine?

Store below 25°C.**

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

**500,000 - 910,000 IU/ml, 0.3 - 0.546 g/ml, 300-546 mg/ml** (this range includes the recommended concentration for injection into the muscle)

* 2°C to 8°C - 48 hours
* below 25°C - 8 hours

**100,000 IU/ml, 0.06 g/ml, 60 mg/ml (the recommended concentration for injection/infusion into the vein)**

* 2°C to 8°C - 24 hours
* below 25°C - 4 hours

From a microbiological point of view, the product should be used immediately. If not used immediately, the storage times and conditions before use are the responsibility of the user and should normally not exceed 24 hours at 2 to 8°C.

**Benzylpenicillin 500,000, 1,000,000, 5,000,000, 10,000,000 IU,**

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• Inflammation of:

* The tissue inside the heart
* The membrane lining the abdominal cavity and covering the abdominal organs
* Meningitis (inflammation of the membranes surrounding the brain and spinal cord)
* The bone marrow
* Abscesses in the brain
* Certain inflammations of the genital organs
* Anthrax
* Tetanus

Gas gangrene

* An infection that primarily spreads through spoiled food called listeriosis
* Pasteurellosis, an infection that can be contracted through contact with infected animals, such as cat bites or scratches
* Rat-bite fever
* Fusospirochaetosis, a specific infection caused by sores on the skin and mucous membranes
* Actinomycosis, also known as 'lumpy jaw'
* Complications of sexually transmitted diseases called gonorrhea and syphilis
* Lyme borreliosis, 'Lyme disease,' an infection caused by a bacterium transmitted by ticks.

**When should you not use this medicine or use it with extra caution?**

When should you not use this medicine?

If you:

* Are allergic to benzylpenicillin
* Have experienced hypersensitivity reactions to penicillin treatment, such as skin rash, itching, fever, shortness of breath, or low blood pressure.
* Do not use Benzylpenicillin if there is a risk of life-threatening allergic shock.
* Have had a severe acute hypersensitivity reaction to other drugs that treat bacterial infections called beta-lactam antibiotics, such as cephalosporin, carbapenem, monobactam.
* When should you take extra caution with this medicine?
* Contact your doctor or pharmacist before using this medicine and during treatment if you:
* Have ever experienced symptoms of intolerance after using other antibiotics, such as cephalosporin. Your doctor will decide whether you can use benzylpenicillin, and a hypersensitivity test is recommended before treatment.
* Are sensitive to allergic reactions (e.g., hives or hay fever) or have asthma. In this case, there is an increased risk of hypersensitivity reactions.
* Have or have had a heart condition or a severe electrolyte imbalance, such as sodium, calcium, potassium, chloride. Your doctor should monitor your electrolyte intake, especially your potassium intake.
* Have impaired liver or kidney function. Your doctor may need to adjust your dosage or the time between two doses.
* Have epilepsy, brain edema, or meningitis. Your doctor will closely monitor you as you are at an increased risk of having a seizure during treatment.
* Have infectious mononucleosis (Pfeiffer's disease). There is an increased risk of skin reactions.
* Have cancer of white blood cells, called acute lymphoblastic leukemia. There is an increased risk of skin reactions.
* Has a fungal skin disease.
* You are at an increased risk of developing allergy-like reactions.
* Takes medications to inhibit blood clotting.
* Control of blood clotting is recommended, and if necessary, the doctor may adjust the dose of the orally administered medicine to inhibit blood clotting.
* Has diabetes.
* The absorption of Benzylpenicillin may be delayed in patients with diabetes when administered intramuscularly.
* Has a sexually transmitted disease and syphilis.
* Your doctor will conduct tests before and during the treatment.
* Is being treated for Lyme borreliosis or complications of syphilis.
* A temporary reaction (the so-called Jarisch-Herxheimer reaction) often occurs due to the bactericidal effect of benzylpenicillin. Symptoms may include sudden fever, chills, skin redness, headache, muscle and joint pain, fatigue, and/or exhaustion. The symptoms may persist for several days. Contact your doctor so they can help alleviate these symptoms.
* Experiences severe, persistent diarrhea during treatment with this medicine.
* This may be due to treatment-related inflammation of the colon. Symptoms include bloody/mucous, watery diarrhea; dull, diffuse to colicky abdominal pain; fever, or, in some cases, constant and painful urge for bowel movements. Your doctor should immediately discontinue the use of Benzylpenicillin and start appropriate treatment.
* Is undergoing a prolonged treatment of several weeks.
* Treatment with Benzylpenicillin may cause excessive growth of certain non-sensitive bacteria or yeast-like fungi. Therefore, inform your doctor if you experience diarrhea, itchy skin rash, or mucous membrane growth caused by yeast-like fungi. Additionally, during prolonged treatment of more than 5 days, your doctor will regularly perform blood tests.
* Is undergoing a laboratory test.
* Treatment with this medicine may influence the results. Therefore, inform your doctor before undergoing a laboratory test about your treatment with this medicine.
* Severe local reactions may occur in infants after intramuscular administration. Therefore, whenever possible, injection in a vein should be performed in this age group.
* Are you using any other medicines?
* If you are using other medicines alongside benzylpenicillin, have done so recently, or are planning to use other medicines in the near future, please inform your doctor or pharmacist.
* It is particularly important to tell your doctor if you are using any of the following medicines:
* Probenecid: for the treatment of gout.
* Indomethacin, phenylbutazone, acetylsalicylic acid, and similar medicines to reduce fever, inflammation, rheumatic conditions, and pain.
* Other medicines to treat bacterial infections.
* Benzylpenicillin only works on certain bacteria. Therefore, Benzylpenicillin should only be combined with other medicines for the treatment of bacterial infections as determined by the doctor.
* Digoxin: to treat heart failure.
* Methotrexate: for the treatment of severe joint inflammation, cancer, and the skin disease psoriasis.
* Combined use of methotrexate and Benzylpenicillin should be avoided where possible. If simultaneous use cannot be avoided, it is recommended to reduce the dose of methotrexate and have the blood level of methotrexate monitored by the doctor. This includes monitoring for possible additional side effects of methotrexate.
* Oral anticoagulant medications, such as acenocoumarol, warfarin. If combined use is required, appropriate blood clotting parameters should be carefully monitored during and after discontinuation of treatment with benzylpenicillin. Dose adjustment of the anticoagulant medication may be necessary.

**Pregnancy and breastfeeding:** Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Please contact your doctor or pharmacist before using this medicine.

**Pregnancy:** The use of Benzylpenicillin is possible during pregnancy if the doctor deems it necessary. However, this medicine is not recommended for the treatment of syphilis during pregnancy.

**Breastfeeding:** Benzylpenicillin is excreted in small amounts in breast milk. Although no side effects have been reported in breastfed infants so far, the possibility should be considered. Inform your doctor immediately if diarrhea, candidiasis, or rash occurs in the child.

For infants who are also receiving formula, the mother should pump and discard the milk during treatment with this medicine. Breastfeeding can be resumed 24 hours after the end of treatment.

**Driving and using machines:** Generally, this medicine does not affect concentration and reaction ability. However, severe side effects, such as severe allergic reactions, may reduce reaction ability. Avoid driving or operating machinery if such severe side effects occur.

**Benzylpenicillin contains sodium:** This medicine contains 1.68 mmol of sodium (main component of table salt) per 1,000,000 IU. This corresponds to 0.1% of the recommended maximum daily intake of sodium for an adult.

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**How to use this medicine?**This medicine is usually administered by a doctor. Your doctor will determine the route of administration, dosage, and dosing interval. Consult your doctor if you are unsure.

**The usual recommended dose is:**

• **Adults and adolescents from 12 years old:** The usual daily dose is 1 to 5 million IU (international units), 0.6-3 g/day, 600-3000 mg/day, divided into 4 to 6 doses. In case of severe infection, the daily dose can be increased to 10 to 40 million IU, 6-24 g/day, 6000-24000 mg/day.

• **Children from 1 month to their 12th birthday:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 4 to 6 doses. In case of severe infection, the daily dose can be increased to 0.1 to 1 million IU per kilogram of body weight, 0.06-0.6 g/kg/day, 60-600 mg/kg/day.

• **Newborn infants from 2 weeks to 1 month old:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 3 to 4 doses. In case of severe infection, the daily dose can be increased to 0.2 to 1 million IU per kilogram of body weight, 0.12-0.6 g/kg/day, 120-600 mg/kg/day.

**• Premature and newborn infants up to 2 weeks old:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 2 doses. In case of severe infection, the daily dose can be increased to 0.2 to 1 million IU per kilogram of body weight, 0.12-0.6 g/kg/day, 120-600 mg/kg/day.

**Patients over 65 years old and patients with impaired kidney or liver function:** The doctor will check kidney and liver function prior to and regularly during treatment. Based on the results, the doctor may adjust the dosage and dosing interval if necessary.

**Duration of treatment and use:** The duration of treatment and use will be determined by the doctor. This depends on the severity of the infection, the bactericidal effect, and the patient's symptoms, which may last for several days to a few weeks.

**Method of administration:** This medicine is usually administered by a doctor.

This medicine can be administered into a muscle or a vein. Intravenous administration can be given as an injection (using a syringe) or as a short-term infusion, usually between 30 and 60 minutes.

**Have you received too much of this medicine:**Tell your doctor if you think you have received too much. Symptoms of overdose may include increased irritability of nerves and muscles or susceptibility to seizures in the brain.

**Have you forgotten to use this medicine?**Contact your doctor immediately.

**Possible side effects**:
Like all medicines, this medicine can have side effects, although not everyone gets them. Contact your doctor immediately if you experience any of the following side effects:

* Rash with blisters and skin peeling all over your body, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson Syndrome). Or a more severe form where your skin peels all over your body (more than 30% of the body's surface area - toxic epidermal necrolysis).
* Flu-like symptoms, such as rash, fever, swollen glands. Unusual blood test results may also be seen, including an increased number of white blood cells (eosinophilia) and liver enzymes in your blood (Drug Reaction with Eosinophilia and Systemic Symptoms - DRESS).
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**Common (affecting less than 1 in 10 users):**

 • Effect on laboratory tests.

**Uncommon (affecting less than 1 in 100 users):**

* Allergic reactions,
* Hives,
* Severe allergic reactions affecting the whole body or causing breathing difficulties, such as asthma, skin bleeding, stomach and intestinal disorders.

**Severe skin reactions, such as:**

* Skin rash with fever and blisters called erythema multiforme
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* Joint pain
* Inflammation of the oral mucosa
* Tong inflammation, black hairy tongue
* Nausea, vomiting.

**Rare (occur in less than 1 in 1000 users):**

* Electrolyte disturbances can occur after rapid infusion of high doses.
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If diarrhea occurs during treatment, the possibility of colitis should be considered. See section 'When should you be extra cautious with this medicine?'.

* Kidney disease
* Abnormal presence of the protein albumin or blood in the urine
* Sediment in the urine called cylindruria
* Reduced urine production or non-excretion of urine. This usually disappears within 48 hours after stopping treatment.
* Severe local reactions during administration into a muscle in infants.

**very rare (occur in less than 1 in 10,000 users):**

* Increased number of white blood cells known as eosinophils
* Decreased number of white blood cells (such as neutrophil granulocytes, granulocytes), hemolytic anemia (reduced blood levels of red blood cells), or both.
* Blood clotting disorders.

**How to store this medicine?

Store below 25°C.**

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* 2°C to 8°C - 48 hours
* below 25°C - 8 hours

**100,000 IU/ml, 0.06 g/ml, 60 mg/ml (the recommended concentration for injection/infusion into the vein)**

* 2°C to 8°C - 24 hours
* below 25°C - 4 hours

From a microbiological point of view, the product should be used immediately. If not used immediately, the storage times and conditions before use are the responsibility of the user and should normally not exceed 24 hours at 2 to 8°C.

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• Inflammation of:

* The tissue inside the heart
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* The bone marrow
* Abscesses in the brain
* Certain inflammations of the genital organs
* Anthrax
* Tetanus

Gas gangrene

* An infection that primarily spreads through spoiled food called listeriosis
* Pasteurellosis, an infection that can be contracted through contact with infected animals, such as cat bites or scratches
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**When should you not use this medicine or use it with extra caution?**

When should you not use this medicine?

If you:

* Are allergic to benzylpenicillin
* Have experienced hypersensitivity reactions to penicillin treatment, such as skin rash, itching, fever, shortness of breath, or low blood pressure.
* Do not use Benzylpenicillin if there is a risk of life-threatening allergic shock.
* Have had a severe acute hypersensitivity reaction to other drugs that treat bacterial infections called beta-lactam antibiotics, such as cephalosporin, carbapenem, monobactam.
* When should you take extra caution with this medicine?
* Contact your doctor or pharmacist before using this medicine and during treatment if you:
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* Are sensitive to allergic reactions (e.g., hives or hay fever) or have asthma. In this case, there is an increased risk of hypersensitivity reactions.
* Have or have had a heart condition or a severe electrolyte imbalance, such as sodium, calcium, potassium, chloride. Your doctor should monitor your electrolyte intake, especially your potassium intake.
* Have impaired liver or kidney function. Your doctor may need to adjust your dosage or the time between two doses.
* Have epilepsy, brain edema, or meningitis. Your doctor will closely monitor you as you are at an increased risk of having a seizure during treatment.
* Have infectious mononucleosis (Pfeiffer's disease). There is an increased risk of skin reactions.
* Have cancer of white blood cells, called acute lymphoblastic leukemia. There is an increased risk of skin reactions.
* Has a fungal skin disease.
* You are at an increased risk of developing allergy-like reactions.
* Takes medications to inhibit blood clotting.
* Control of blood clotting is recommended, and if necessary, the doctor may adjust the dose of the orally administered medicine to inhibit blood clotting.
* Has diabetes.
* The absorption of Benzylpenicillin may be delayed in patients with diabetes when administered intramuscularly.
* Has a sexually transmitted disease and syphilis.
* Your doctor will conduct tests before and during the treatment.
* Is being treated for Lyme borreliosis or complications of syphilis.
* A temporary reaction (the so-called Jarisch-Herxheimer reaction) often occurs due to the bactericidal effect of benzylpenicillin. Symptoms may include sudden fever, chills, skin redness, headache, muscle and joint pain, fatigue, and/or exhaustion. The symptoms may persist for several days. Contact your doctor so they can help alleviate these symptoms.
* Experiences severe, persistent diarrhea during treatment with this medicine.
* This may be due to treatment-related inflammation of the colon. Symptoms include bloody/mucous, watery diarrhea; dull, diffuse to colicky abdominal pain; fever, or, in some cases, constant and painful urge for bowel movements. Your doctor should immediately discontinue the use of Benzylpenicillin and start appropriate treatment.
* Is undergoing a prolonged treatment of several weeks.
* Treatment with Benzylpenicillin may cause excessive growth of certain non-sensitive bacteria or yeast-like fungi. Therefore, inform your doctor if you experience diarrhea, itchy skin rash, or mucous membrane growth caused by yeast-like fungi. Additionally, during prolonged treatment of more than 5 days, your doctor will regularly perform blood tests.
* Is undergoing a laboratory test.
* Treatment with this medicine may influence the results. Therefore, inform your doctor before undergoing a laboratory test about your treatment with this medicine.
* Severe local reactions may occur in infants after intramuscular administration. Therefore, whenever possible, injection in a vein should be performed in this age group.
* Are you using any other medicines?
* If you are using other medicines alongside benzylpenicillin, have done so recently, or are planning to use other medicines in the near future, please inform your doctor or pharmacist.
* It is particularly important to tell your doctor if you are using any of the following medicines:
* Probenecid: for the treatment of gout.
* Indomethacin, phenylbutazone, acetylsalicylic acid, and similar medicines to reduce fever, inflammation, rheumatic conditions, and pain.
* Other medicines to treat bacterial infections.
* Benzylpenicillin only works on certain bacteria. Therefore, Benzylpenicillin should only be combined with other medicines for the treatment of bacterial infections as determined by the doctor.
* Digoxin: to treat heart failure.
* Methotrexate: for the treatment of severe joint inflammation, cancer, and the skin disease psoriasis.
* Combined use of methotrexate and Benzylpenicillin should be avoided where possible. If simultaneous use cannot be avoided, it is recommended to reduce the dose of methotrexate and have the blood level of methotrexate monitored by the doctor. This includes monitoring for possible additional side effects of methotrexate.
* Oral anticoagulant medications, such as acenocoumarol, warfarin. If combined use is required, appropriate blood clotting parameters should be carefully monitored during and after discontinuation of treatment with benzylpenicillin. Dose adjustment of the anticoagulant medication may be necessary.

**Pregnancy and breastfeeding:** Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Please contact your doctor or pharmacist before using this medicine.

**Pregnancy:** The use of Benzylpenicillin is possible during pregnancy if the doctor deems it necessary. However, this medicine is not recommended for the treatment of syphilis during pregnancy.

**Breastfeeding:** Benzylpenicillin is excreted in small amounts in breast milk. Although no side effects have been reported in breastfed infants so far, the possibility should be considered. Inform your doctor immediately if diarrhea, candidiasis, or rash occurs in the child.

For infants who are also receiving formula, the mother should pump and discard the milk during treatment with this medicine. Breastfeeding can be resumed 24 hours after the end of treatment.

**Driving and using machines:** Generally, this medicine does not affect concentration and reaction ability. However, severe side effects, such as severe allergic reactions, may reduce reaction ability. Avoid driving or operating machinery if such severe side effects occur.

**Benzylpenicillin contains sodium:** This medicine contains 1.68 mmol of sodium (main component of table salt) per 1,000,000 IU. This corresponds to 0.1% of the recommended maximum daily intake of sodium for an adult.

[**500,000 IU powder for solution for injection/infusion]:** This medicine contains less than 1 mmol of sodium (23 mg) per vial, making it essentially 'sodium-free'.

**[1,000,000 IU powder for solution for injection/infusion]:** This medicine contains 38.6 mg of sodium per vial, equivalent to 1.9% of the WHO-recommended maximum daily intake of 2 g of sodium for an adult.

**[5,000,000 IU powder for solution for injection/infusion]:** This medicine contains 193 mg of sodium per vial, equivalent to 9.7% of the WHO-recommended maximum daily intake of 2 g of sodium for an adult.

**[10,000,000 IU powder for solution for injection/infusion]:** This medicine contains 386 mg of sodium per vial, equivalent to 19.3% of the WHO-recommended maximum daily intake of 2 g of sodium for an adult.

**How to use this medicine?**This medicine is usually administered by a doctor. Your doctor will determine the route of administration, dosage, and dosing interval. Consult your doctor if you are unsure.

**The usual recommended dose is:**

• **Adults and adolescents from 12 years old:** The usual daily dose is 1 to 5 million IU (international units), 0.6-3 g/day, 600-3000 mg/day, divided into 4 to 6 doses. In case of severe infection, the daily dose can be increased to 10 to 40 million IU, 6-24 g/day, 6000-24000 mg/day.

• **Children from 1 month to their 12th birthday:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 4 to 6 doses. In case of severe infection, the daily dose can be increased to 0.1 to 1 million IU per kilogram of body weight, 0.06-0.6 g/kg/day, 60-600 mg/kg/day.

• **Newborn infants from 2 weeks to 1 month old:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 3 to 4 doses. In case of severe infection, the daily dose can be increased to 0.2 to 1 million IU per kilogram of body weight, 0.12-0.6 g/kg/day, 120-600 mg/kg/day.

**• Premature and newborn infants up to 2 weeks old:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 2 doses. In case of severe infection, the daily dose can be increased to 0.2 to 1 million IU per kilogram of body weight, 0.12-0.6 g/kg/day, 120-600 mg/kg/day.

**Patients over 65 years old and patients with impaired kidney or liver function:** The doctor will check kidney and liver function prior to and regularly during treatment. Based on the results, the doctor may adjust the dosage and dosing interval if necessary.

**Duration of treatment and use:** The duration of treatment and use will be determined by the doctor. This depends on the severity of the infection, the bactericidal effect, and the patient's symptoms, which may last for several days to a few weeks.

**Method of administration:** This medicine is usually administered by a doctor.

This medicine can be administered into a muscle or a vein. Intravenous administration can be given as an injection (using a syringe) or as a short-term infusion, usually between 30 and 60 minutes.

**Have you received too much of this medicine:**Tell your doctor if you think you have received too much. Symptoms of overdose may include increased irritability of nerves and muscles or susceptibility to seizures in the brain.

**Have you forgotten to use this medicine?**Contact your doctor immediately.

**Possible side effects**:
Like all medicines, this medicine can have side effects, although not everyone gets them. Contact your doctor immediately if you experience any of the following side effects:

* Rash with blisters and skin peeling all over your body, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson Syndrome). Or a more severe form where your skin peels all over your body (more than 30% of the body's surface area - toxic epidermal necrolysis).
* Flu-like symptoms, such as rash, fever, swollen glands. Unusual blood test results may also be seen, including an increased number of white blood cells (eosinophilia) and liver enzymes in your blood (Drug Reaction with Eosinophilia and Systemic Symptoms - DRESS).
* A red, scaly rash with bumps under the skin and blisters (exanthemateuze pustulose).
* Severe allergic reactions (anaphylactic reactions or angioedema) that can occur as:
* Skin rash or itchy skin, breathing difficulties or tightness in the chest, swollen eyelids, face, or lips, swelling or redness of the tongue, fever, joint pain, swollen lymph nodes.
* Side effects can occur with the following frequencies:

**Common (affecting less than 1 in 10 users):**

 • Effect on laboratory tests.

**Uncommon (affecting less than 1 in 100 users):**

* Allergic reactions,
* Hives,
* Severe allergic reactions affecting the whole body or causing breathing difficulties, such as asthma, skin bleeding, stomach and intestinal 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 oral mucosa
* Tong inflammation, black hairy tongue
* Nausea, vomiting.

**Rare (occur in less than 1 in 1000 users):**

* Electrolyte disturbances can occur after rapid infusion of high doses.
* Nerve disorders
* Convulsive reactions can occur after infusion of high doses. This should be taken into account, especially in patients with severe renal insufficiency, epilepsy, meningitis, or cerebral edema. This also applies to patients in whom a machine temporarily takes over the function of the heart and lungs during surgery.
* Diarrhea

If diarrhea occurs during treatment, the possibility of colitis should be considered. See section 'When should you be extra cautious with this medicine?'.

* Kidney disease
* Abnormal presence of the protein albumin or blood in the urine
* Sediment in the urine called cylindruria
* Reduced urine production or non-excretion of urine. This usually disappears within 48 hours after stopping treatment.
* Severe local reactions during administration into a muscle in infants.

**very rare (occur in less than 1 in 10,000 users):**

* Increased number of white blood cells known as eosinophils
* Decreased number of white blood cells (such as neutrophil granulocytes, granulocytes), hemolytic anemia (reduced blood levels of red blood cells), or both.
* Blood clotting disorders.

**How to store this medicine?

Store below 25°C.**

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

**500,000 - 910,000 IU/ml, 0.3 - 0.546 g/ml, 300-546 mg/ml** (this range includes the recommended concentration for injection into the muscle)

* 2°C to 8°C - 48 hours
* below 25°C - 8 hours

**100,000 IU/ml, 0.06 g/ml, 60 mg/ml (the recommended concentration for injection/infusion into the vein)**

* 2°C to 8°C - 24 hours
* below 25°C - 4 hours

From a microbiological point of view, the product should be used immediately. If not used immediately, the storage times and conditions before use are the responsibility of the user and should normally not exceed 24 hours at 2 to 8°C.

**Benzylpenicillin 500,000, 1,000,000, 5,000,000, 10,000,000 IU,**

**What is Benzylpenicillin, and what is this medicine used for?**

Benzylpenicillin is a medicine used to treat infections caused by benzylpenicillin-sensitive bacteria. This medicine is used for the treatment of adults, adolescents, children, newborn infants, and premature infants.

Benzylpenicillin is used for the following bacterial infections:

* Skin and wound infections
* Diphtheria
* Pneumonia
* Accumulation of pus in body cavities
* Infections of the superficial layer of the skin that appear as a well-defined extensive redness called Erysipelas

• Inflammation of:

* The tissue inside the heart
* The membrane lining the abdominal cavity and covering the abdominal organs
* Meningitis (inflammation of the membranes surrounding the brain and spinal cord)
* The bone marrow
* Abscesses in the brain
* Certain inflammations of the genital organs
* Anthrax
* Tetanus

Gas gangrene

* An infection that primarily spreads through spoiled food called listeriosis
* Pasteurellosis, an infection that can be contracted through contact with infected animals, such as cat bites or scratches
* Rat-bite fever
* Fusospirochaetosis, a specific infection caused by sores on the skin and mucous membranes
* Actinomycosis, also known as 'lumpy jaw'
* Complications of sexually transmitted diseases called gonorrhea and syphilis
* Lyme borreliosis, 'Lyme disease,' an infection caused by a bacterium transmitted by ticks.

**When should you not use this medicine or use it with extra caution?**

When should you not use this medicine?

If you:

* Are allergic to benzylpenicillin
* Have experienced hypersensitivity reactions to penicillin treatment, such as skin rash, itching, fever, shortness of breath, or low blood pressure.
* Do not use Benzylpenicillin if there is a risk of life-threatening allergic shock.
* Have had a severe acute hypersensitivity reaction to other drugs that treat bacterial infections called beta-lactam antibiotics, such as cephalosporin, carbapenem, monobactam.
* When should you take extra caution with this medicine?
* Contact your doctor or pharmacist before using this medicine and during treatment if you:
* Have ever experienced symptoms of intolerance after using other antibiotics, such as cephalosporin. Your doctor will decide whether you can use benzylpenicillin, and a hypersensitivity test is recommended before treatment.
* Are sensitive to allergic reactions (e.g., hives or hay fever) or have asthma. In this case, there is an increased risk of hypersensitivity reactions.
* Have or have had a heart condition or a severe electrolyte imbalance, such as sodium, calcium, potassium, chloride. Your doctor should monitor your electrolyte intake, especially your potassium intake.
* Have impaired liver or kidney function. Your doctor may need to adjust your dosage or the time between two doses.
* Have epilepsy, brain edema, or meningitis. Your doctor will closely monitor you as you are at an increased risk of having a seizure during treatment.
* Have infectious mononucleosis (Pfeiffer's disease). There is an increased risk of skin reactions.
* Have cancer of white blood cells, called acute lymphoblastic leukemia. There is an increased risk of skin reactions.
* Has a fungal skin disease.
* You are at an increased risk of developing allergy-like reactions.
* Takes medications to inhibit blood clotting.
* Control of blood clotting is recommended, and if necessary, the doctor may adjust the dose of the orally administered medicine to inhibit blood clotting.
* Has diabetes.
* The absorption of Benzylpenicillin may be delayed in patients with diabetes when administered intramuscularly.
* Has a sexually transmitted disease and syphilis.
* Your doctor will conduct tests before and during the treatment.
* Is being treated for Lyme borreliosis or complications of syphilis.
* A temporary reaction (the so-called Jarisch-Herxheimer reaction) often occurs due to the bactericidal effect of benzylpenicillin. Symptoms may include sudden fever, chills, skin redness, headache, muscle and joint pain, fatigue, and/or exhaustion. The symptoms may persist for several days. Contact your doctor so they can help alleviate these symptoms.
* Experiences severe, persistent diarrhea during treatment with this medicine.
* This may be due to treatment-related inflammation of the colon. Symptoms include bloody/mucous, watery diarrhea; dull, diffuse to colicky abdominal pain; fever, or, in some cases, constant and painful urge for bowel movements. Your doctor should immediately discontinue the use of Benzylpenicillin and start appropriate treatment.
* Is undergoing a prolonged treatment of several weeks.
* Treatment with Benzylpenicillin may cause excessive growth of certain non-sensitive bacteria or yeast-like fungi. Therefore, inform your doctor if you experience diarrhea, itchy skin rash, or mucous membrane growth caused by yeast-like fungi. Additionally, during prolonged treatment of more than 5 days, your doctor will regularly perform blood tests.
* Is undergoing a laboratory test.
* Treatment with this medicine may influence the results. Therefore, inform your doctor before undergoing a laboratory test about your treatment with this medicine.
* Severe local reactions may occur in infants after intramuscular administration. Therefore, whenever possible, injection in a vein should be performed in this age group.
* Are you using any other medicines?
* If you are using other medicines alongside benzylpenicillin, have done so recently, or are planning to use other medicines in the near future, please inform your doctor or pharmacist.
* It is particularly important to tell your doctor if you are using any of the following medicines:
* Probenecid: for the treatment of gout.
* Indomethacin, phenylbutazone, acetylsalicylic acid, and similar medicines to reduce fever, inflammation, rheumatic conditions, and pain.
* Other medicines to treat bacterial infections.
* Benzylpenicillin only works on certain bacteria. Therefore, Benzylpenicillin should only be combined with other medicines for the treatment of bacterial infections as determined by the doctor.
* Digoxin: to treat heart failure.
* Methotrexate: for the treatment of severe joint inflammation, cancer, and the skin disease psoriasis.
* Combined use of methotrexate and Benzylpenicillin should be avoided where possible. If simultaneous use cannot be avoided, it is recommended to reduce the dose of methotrexate and have the blood level of methotrexate monitored by the doctor. This includes monitoring for possible additional side effects of methotrexate.
* Oral anticoagulant medications, such as acenocoumarol, warfarin. If combined use is required, appropriate blood clotting parameters should be carefully monitored during and after discontinuation of treatment with benzylpenicillin. Dose adjustment of the anticoagulant medication may be necessary.

**Pregnancy and breastfeeding:** Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Please contact your doctor or pharmacist before using this medicine.

**Pregnancy:** The use of Benzylpenicillin is possible during pregnancy if the doctor deems it necessary. However, this medicine is not recommended for the treatment of syphilis during pregnancy.

**Breastfeeding:** Benzylpenicillin is excreted in small amounts in breast milk. Although no side effects have been reported in breastfed infants so far, the possibility should be considered. Inform your doctor immediately if diarrhea, candidiasis, or rash occurs in the child.

For infants who are also receiving formula, the mother should pump and discard the milk during treatment with this medicine. Breastfeeding can be resumed 24 hours after the end of treatment.

**Driving and using machines:** Generally, this medicine does not affect concentration and reaction ability. However, severe side effects, such as severe allergic reactions, may reduce reaction ability. Avoid driving or operating machinery if such severe side effects occur.

**Benzylpenicillin contains sodium:** This medicine contains 1.68 mmol of sodium (main component of table salt) per 1,000,000 IU. This corresponds to 0.1% of the recommended maximum daily intake of sodium for an adult.

[**500,000 IU powder for solution for injection/infusion]:** This medicine contains less than 1 mmol of sodium (23 mg) per vial, making it essentially 'sodium-free'.

**[1,000,000 IU powder for solution for injection/infusion]:** This medicine contains 38.6 mg of sodium per vial, equivalent to 1.9% of the WHO-recommended maximum daily intake of 2 g of sodium for an adult.

**[5,000,000 IU powder for solution for injection/infusion]:** This medicine contains 193 mg of sodium per vial, equivalent to 9.7% of the WHO-recommended maximum daily intake of 2 g of sodium for an adult.

**[10,000,000 IU powder for solution for injection/infusion]:** This medicine contains 386 mg of sodium per vial, equivalent to 19.3% of the WHO-recommended maximum daily intake of 2 g of sodium for an adult.

**How to use this medicine?**This medicine is usually administered by a doctor. Your doctor will determine the route of administration, dosage, and dosing interval. Consult your doctor if you are unsure.

**The usual recommended dose is:**

• **Adults and adolescents from 12 years old:** The usual daily dose is 1 to 5 million IU (international units), 0.6-3 g/day, 600-3000 mg/day, divided into 4 to 6 doses. In case of severe infection, the daily dose can be increased to 10 to 40 million IU, 6-24 g/day, 6000-24000 mg/day.

• **Children from 1 month to their 12th birthday:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 4 to 6 doses. In case of severe infection, the daily dose can be increased to 0.1 to 1 million IU per kilogram of body weight, 0.06-0.6 g/kg/day, 60-600 mg/kg/day.

• **Newborn infants from 2 weeks to 1 month old:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 3 to 4 doses. In case of severe infection, the daily dose can be increased to 0.2 to 1 million IU per kilogram of body weight, 0.12-0.6 g/kg/day, 120-600 mg/kg/day.

**• Premature and newborn infants up to 2 weeks old:** The usual daily dose is 0.03 to 0.1 million IU per kilogram of body weight, 0.018-0.06 g/kg/day, 18-60 mg/kg/day, divided into 2 doses. In case of severe infection, the daily dose can be increased to 0.2 to 1 million IU per kilogram of body weight, 0.12-0.6 g/kg/day, 120-600 mg/kg/day.

**Patients over 65 years old and patients with impaired kidney or liver function:** The doctor will check kidney and liver function prior to and regularly during treatment. Based on the results, the doctor may adjust the dosage and dosing interval if necessary.

**Duration of treatment and use:** The duration of treatment and use will be determined by the doctor. This depends on the severity of the infection, the bactericidal effect, and the patient's symptoms, which may last for several days to a few weeks.

**Method of administration:** This medicine is usually administered by a doctor.

This medicine can be administered into a muscle or a vein. Intravenous administration can be given as an injection (using a syringe) or as a short-term infusion, usually between 30 and 60 minutes.

**Have you received too much of this medicine:**Tell your doctor if you think you have received too much. Symptoms of overdose may include increased irritability of nerves and muscles or susceptibility to seizures in the brain.

**Have you forgotten to use this medicine?**Contact your doctor immediately.

**Possible side effects**:
Like all medicines, this medicine can have side effects, although not everyone gets them. Contact your doctor immediately if you experience any of the following side effects:

* Rash with blisters and skin peeling all over your body, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson Syndrome). Or a more severe form where your skin peels all over your body (more than 30% of the body's surface area - toxic epidermal necrolysis).
* Flu-like symptoms, such as rash, fever, swollen glands. Unusual blood test results may also be seen, including an increased number of white blood cells (eosinophilia) and liver enzymes in your blood (Drug Reaction with Eosinophilia and Systemic Symptoms - DRESS).
* A red, scaly rash with bumps under the skin and blisters (exanthemateuze pustulose).
* Severe allergic reactions (anaphylactic reactions or angioedema) that can occur as:
* Skin rash or itchy skin, breathing difficulties or tightness in the chest, swollen eyelids, face, or lips, swelling or redness of the tongue, fever, joint pain, swollen lymph nodes.
* Side effects can occur with the following frequencies:

**Common (affecting less than 1 in 10 users):**

 • Effect on laboratory tests.

**Uncommon (affecting less than 1 in 100 users):**

* Allergic reactions,
* Hives,
* Severe allergic reactions affecting the whole body or causing breathing difficulties, such as asthma, skin bleeding, stomach and intestinal 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 oral mucosa
* Tong inflammation, black hairy tongue
* Nausea, vomiting.

**Rare (occur in less than 1 in 1000 users):**

* Electrolyte disturbances can occur after rapid infusion of high doses.
* Nerve disorders
* Convulsive reactions can occur after infusion of high doses. This should be taken into account, especially in patients with severe renal insufficiency, epilepsy, meningitis, or cerebral edema. This also applies to patients in whom a machine temporarily takes over the function of the heart and lungs during surgery.
* Diarrhea

If diarrhea occurs during treatment, the possibility of colitis should be considered. See section 'When should you be extra cautious with this medicine?'.

* Kidney disease
* Abnormal presence of the protein albumin or blood in the urine
* Sediment in the urine called cylindruria
* Reduced urine production or non-excretion of urine. This usually disappears within 48 hours after stopping treatment.
* Severe local reactions during administration into a muscle in infants.

**very rare (occur in less than 1 in 10,000 users):**

* Increased number of white blood cells known as eosinophils
* Decreased number of white blood cells (such as neutrophil granulocytes, granulocytes), hemolytic anemia (reduced blood levels of red blood cells), or both.
* Blood clotting disorders.

**How to store this medicine?

Store below 25°C.**

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

**500,000 - 910,000 IU/ml, 0.3 - 0.546 g/ml, 300-546 mg/ml** (this range includes the recommended concentration for injection into the muscle)

* 2°C to 8°C - 48 hours
* below 25°C - 8 hours

**100,000 IU/ml, 0.06 g/ml, 60 mg/ml (the recommended concentration for injection/infusion into the vein)**

* 2°C to 8°C - 24 hours
* below 25°C - 4 hours

From a microbiological point of view, the product should be used immediately. If not used immediately, the storage times and conditions before use are the responsibility of the user and should normally not exceed 24 hours at 2 to 8°C.