Penicillin-G-Natrium

180 mg/ml, powder and solvent to prepare a solution for injection

Target species: Cattle, pigs, dogs and cats

Active ingredient: benzylpenicillin sodium

Name and address of the marketing authorisation holder:
Bela-Pharm GmbH & Co. KG
Lohner Str. 19, 49377 Vechta - Germany

Name of the veterinary medicinal product:
Penicillin-G-Natrium
180 mg/ml, powder and solvent to prepare a solution for injection
for cattle, pigs, dogs and cats.
Active ingredient: benzylpenicillin sodium

Statement of the active substance(s) and other ingredient(s):
1 vial with powder contains:
Pharmacological active substance:

Benzylpenicillin sodium	8.985 g
(equivalent to	15 000 000 I.U.)

1 ml solvent contains:

Water for injection	1.0 ml

1 ml of the ready-to-use solution contains:

Benzylpenicillin sodium	180 mg
(equivalent to	300.000 I.U.)

Pharmaceutical form:
Powder and solvent to prepare a solution for injection.
Powder: white to almost white powder.
Solvent: clear, colourless solution.
Ready-to-use solution: clear solution for injection.

Indications:
Treatment of the following diseases in *cattle, calves, pigs, dogs* and *cats* caused by bacteria sensitive to benzylpenicillin:
Cattle:
Acute and chronic mastitis with disturbances of the general state of health.

Calf:
Infections of the respiratory tract, inflammations of the navel and the joints.

Pig:
Erysipelas, fibrineous inflammation of the serosa and joints (Glässer's disease).

Dog, cat:
Tonsilitis, pyodermia, diseases of the mucosa caused by fusobacteria and spirochaetes (Plaut Vincenti).

Contraindications:
Resistance to penicillins.
Presence of β-lactamase producing germs.
Do not use in animals with known hypersensitivity to penicillins, cephalosporins, other beta-lactam antibiotics or to any of the excipients.
Severe renal dysfunction with anuria and oliguria.
Do not use concomitantly with antibiotics acting bacteriostatic.
Do not use in guinea pigs, hamsters or other small rodents. Penicillin must not be used in these animal species because they may impact the intestinal flora with possible lethal outcome.

Adverse reactions (frequency and seriousness):
Allergic reactions (allergic skin reactions, anaphylaxis).
If allergic reactions occur, discontinue the treatment with the pharmaceutical immediately and treat symptomatically (see overdose).
Coutermeasures to be taken in case of an allergic reaction:
In anaphylaxis: adrenaline and/or glucorticoids.
In allergic skin reactions: antihistaminics and/or glucorticoids.

Target species:
Cattle, *calf*, *pig*, *dog* and *cat*.

Dosage for each species, route(s) and method of administration:
For intramuscular injection in *cattle, calf, pig, dog* and *cat:*

Minimal single dose:
Cattle, calf, pig, dog and *cat:* 10 000 I.U. / kg body weight

Daily dose:
Cattle, calf, pig: 25 000 I.U. / kg body weight
Dog and cat: 50 000 - 100 000 I.U. / kg body weight

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal.
Depending on the severity of the disease, a treatment in intervals of 4-6 hours might be necessary.
Should there be no significant improvement of the state of health after 3 days of treatment, reconsider diagnosis, if necessary, a change in therapy must be considered.
It is of importance to continue the treatment for two additional days after cessation of the clinical symptoms.

Advice on correct administration:
Special warnings for each target species:
Not indicated.
Special precautions for use in animals:
Use of the veterinary medicinal product should be based on susceptibility testing of the bacteria isolated from the animal.

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
An increased use, including a use of the product deviating from the instructions given in the SPC and product information may increase the prevalence of bacteria resistant to penicillin and may decrease the effectiveness of treatment with other anitimicrobials (cephalosporins and other beta-lactam antibiotics), due to the potential for cross-resistance.
In the target animal species cattle and pig, the daily dose as given in section 8 must be observed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause hypersensitivity (allergic) reactions following inadvertent injection, inhalation, oral intake or absorption via the skin. Hypersensitivity to penicillin may be linked to a cross reaction to other penicillins and cephalosporins and vice versa. Allergic reactions to these substances may be life-threatening in rare cases.
Do not handle this veterinary medicinal product, when you know that you are sensitive to penicillins and/or cephalosporins or when you have been instructed not to handle such preparations.
Handle this veterinary medicinal product with great care and avoid inadvertent contact with the skin or the eyes. Persons who show a reaction following contact with the preparation shall avoid to handle this veterinary medicinal product or other veterinary medicinal product containing penicillins or cephalosporins.
It is recommended to wear gloves when handling the veterinary medicinal product. Parts of skins exposed to the veterinary medicinal product should be washed with water. In the case of a contat with the eyes, these should be rinsed with plenty of clean running water.
In case you observe symptoms as skin rush following exposition, seek advice of a medical doctor and show these warning instructions. Facial oedema, swelling of the lips or the eyes or respiratory distress are severe symptoms and require immediate medical care.

Use during pregnancy, lactation or lay:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
The mixture with other pharmaceutical products in one syringe must be avoided because of possible chemical/physical incompatibilities.
Regarding the antibacterial activity, an antagonism between penicillins and chemotherapeutic agents with instantaneous bacteriostatic activity is possible.
The activity of aminoglycosids is increased by penicillins.
The excretion of benzylpenicillin is prolonged by phenylbutazone and acetylsalicylic acid.
Watersoluble penicillins are incompatible with metal ions, amino acids, ascorbic acid, heparin and the vitamin B-complex.

Overdose (symptoms, emergency procedures, antidotes):
Following overdose, allergic reactions as well as central nervous symptoms of excitement and convulsions may occur. Immediately discontinue the treatment with Penicillin-G-Natrium and treat symptomatically.

In anaphylaxis:	adrenaline and/or glucorticoids.
In allergic skin reactions:	antihistaminics and/or glucorticoids.
In convulsions:	administration of barbiturates.

An early termination of the medication must be in agreement with the responsible veterinarian, as an untimely termination may support the development of resistant bacterial strains.

Incompatibilities:
As no studies on incompatibilities were performed, this veterinary medicinal product shall not be mixed with other pharmaceuticals.

Withdrawal period(s):

Cattle, *pig*:	Edible tissues:	5 days
	Milk (cattle):	4 days

Special storage precautions:
Keep out of reach and sight of children.
Shelf life after dilution or reconstitution according to directions:
Residual amounts remaining following reconstitution of the pharmaceutical form are to be wasted.
Do not use after the expiration date stated on the label.

Special warnings:
None.

Special precautions for the disposal of unused product or waste materials:
Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with waste water or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

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For animal treatment only.

Available on prescription only!