Belamox®

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

Target species: cattle, horses and pigs

Active ingredient: Amoxicillin in form amoxicillin sodium

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

Composition:
1 vial with powder contains:
Pharmacological active substance:
Amoxicillin sodium 5.3 g
1 ml solvent contains:
Water for injection 1.0 ml

1 ml of the ready-to-use solution contains:
Amoxicillin sodium 213 mg
(equivalent to 200 mg amoxicillin)

Pharmaceutical form:
powder and solvent to prepare a solution for intramuscular, intravenous, or subcutaneous injection.

Powder: white to almost white powder.
Solvent: clear, colourless solution.

Ready-to-use solution: when preparing the solution, a transient rose colouration may occur. The ready-to-use solution is clear and colourless to slightly yellowish.

Pharmacotherapeutic group: β-lactam antibiotic

Target species: *Cattle*, *calf*, *horse*, and *pig*.

Indications:
Treatment of the following diseases in *cattle*, *calves*, *horses* and *pigs* caused by gram-positive and /or gram-negative bacteria sensitive to amoxicillin:
- Infections of the lung and the upper respiratory tract,
- Infections of the gastro-intestinal tract,
- Secondary infections in viral infections.

Contraindications:
Do not use in animals with known hypersensitivity to penicillins and other substances of the β-lactam group.
Severe renal dysfunction with anuria and oliguria.
Presence of ß-lactamase producing germs.
Do not use in *guinea pigs*, *hamsters*, *rabbits*, and other *small rodents*.
Do not use concomitantly with antibiotics acting bacteriostatic.

Adverse reactions:
In rare cases local irritation may occur following injection of Amoxicillin.
Allergic reactions (allergic skin reactions, anaphylaxis).
If allergic reactions occur, discontinue the treatment with Belamox immediately and treat symptomatically (see overdose).

Dosage for each species, route(s) and method of administration:
Cattle, *calf*, *horse*, and *pig*:
10 mg / kg body weight, equivalent to:
1 ml / 20 kg b.w. every 12 hours intravenously (exept *pigs*), intramuscularly or subcutaneously.
1 ml solution corresponds to 200 mg Amoxicillin.
The contents of the vial is solved in 21.6 ml water for injection.
Shake well until a clear solution is obtained.
In the solved form amoxicillin is only stable for a short period of time.
It must therefore be used up immediately after dissolution.
Intramuscular injection, in *pigs* preferably into the lateral neck, in *calves* in the *Musculus anconaeus*.
Duration of treatment: at least 3 days.
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.

Withdrawal period(s):
Following intravenous injection:

Cattle, *calf*, *horse*:	Edible tissues:	5 days
	Milk:	24 hours

Following intramuscular or subcutaneous injection:

Cattle, *calf*, *pig*:	Edible tissues:	9 days
Horse:	Edible tissues:	16 days
	Milk:	3 days

Special warnings:
Special precautions for use:
Special precautions for use in animals:
Intravenous injection must be executed slowly, as the risk of shock is increased.
The veterinary medicinal product shall be used under consideration of an antibiogram.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause an allergic reaction, which may be life-threatening following inadvertent inhalation, oral intake or absorption via the skin. A cross reaction with different molecules of the class of substances is possible. Therefore persons with known hypersensitivity to penicillins or cephalosporins shall not handle such products. Each direct contact is to be avoided. On the incidence of allergic reactions a medical doctor shall be consulted immediately.

Use during pregnancy, lactation or lay:
Not indicated.

Interaction with other medicinal products and other forms of interaction:
Mixing with other medicinal products should be avoided due to possible incompatibilities.

Overdose (symptoms, emergency procedures, antidotes):
Following overdose, allergic reactions as well as central nervous symptoms of excitement and seizures may occur. Immediately discontinue the treatment with Belamox and treat symptomatically. No specific antidote known.
In anaphylaxis: adrenaline and/or glucorticoids i.v./i.m.
In allergic skin reactions: antihistaminics and/or glucorticoids.
In spasms: administration of barbiturates.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary pharmaceutical products.

Special storage precautions:
Do not store above 30 °C.
Keep out of reach and sight of children.
Residual amounts remaining in the vial after reconstitution are to be wasted.

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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Other informations:
1 OP with 1 vial with 5.3 g powder and 1 vial with 21.6 ml solvent.
1 OP with 6 vials with 5.3 g powder and 6 vials with 21.6 ml solvent.
Not all pack sizes may be marketed.

For animal treatment only.

Available on prescription only!