

COFAMOX 15 L.A SUSPENSION FOR INJECTION

Composition:

Amoxicillin (as trihydrate) 150 mg
Excipient qs 1 ml

Product Description: Suspension with a greyish beige sediment and an almost colourless supernatant.

Pharmacodynamics: Amoxicillin is a semisynthetic penicillin. It is a compound slightly acid, slightly liposoluble, stable in acid medium. Amoxicillin exerts a bactericidal effect. The alterations it causes in the bacterial cell wall result in osmotic lysis of the cell. Amoxicillin having a relatively wide spectrum, numerous species sensitive to it are reported in clinical practice. The predominant effect is exerted against Gram-positive bacteria, but certain Gram-negative bacteria, notably, *Pasteurella multocida* and *Mannheimia haemolytica* which are particularly susceptible to the amoxicillin bactericidal effect.

The susceptible species of clinical importance in veterinary practice are the following: *Staphylococcus spp.*, *Streptococcus spp.*, *Corynebacterium spp.*, *Escherichia spp.*, *Haemophilus spp.*, *Klebsiella spp.*, *Shigella spp.*, *Salmonella spp.*, *Proteus spp.*, *Mannheimia haemolytica* and *Pasteurella spp.*. In an original study on 21 strains of *Pasteurella multocida* and 60 strains of *Mannheimia haemolytica* of bovine origin, the mean values for the following MIC have been obtained:

Bacterial species	MIC ₅₀	MIC ₉₀
<i>Pasteurella multocida</i>	0.06 - < 0.125 µg/ml	0.06 - < 0.125 µg/ml
<i>Mannheimia haemolytica</i>	0.083 µg/ml	0.115 µg/ml

Pharmacokinetics: Following intramuscular administration of the veterinary medicinal product, amoxicillin is well absorbed with a systemic bioavailability included between 60 and 100%. The mean half-life absorption rate is from 67 to 103 min and the plasma peak concentration is about 3 µg/ml, it is observed 2 to 3 hours after administration. Between 2 injections, the plasma concentrations are maintained above MIC₅₀ during more than two thirds of the time and until 36 hours after the second injection. Amoxicillin is well distributed in the body with a distribution volume near to 0.55 l/kg and a total clearance near 5 ml/min/kg.

Indication: Cattle : Treatment of respiratory infections due to *Pasteurella multocida* and *Mannheimia haemolytica*.

Routes of administration: Intramuscular injection.

Dosage: 5 mg of amoxicillin per kg of live weight, by intramuscular route, equivalent to 1 ml of suspension per 10 kg of live weight, twice at 48 hours interval.

It is recommended that the volume administered per site of injection should not exceed 20ml. Shake well before use in order to homogenize the suspension.

Contraindications:

Do not use in animals with known hypersensitivity to penicillin or other substances of the beta-lactam group. Do not use in rabbits, guinea-pigs, hamsters and gerbils. Do not use in case of known resistance of *Pasteurella multocida* or *Mannheimia haemolytica* to amoxicillin.

Warnings and Precautions:

Special warnings for each target species

None

Special precautions for use in animals

Inject under strict asepsis.

In case of the occurrence of allergic reaction, the treatment should be withdrawn immediately.

In animals with renal or hepatic deficiencies, the dosage regimen should be evaluated carefully.

Due to resistance cases of *Pasteurella multocida* or *Mannheimia haemolytica*, the use of the veterinary medicinal product should be based on a susceptibility testing. Inappropriate use of the product may increase the prevalence of the bacteria resistant to amoxicillin and may decrease the effectiveness of treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reaction to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

People with known hypersensitivity to penicillins should avoid contact with the product. In case of accidental contact with skin or eyes, rinse immediately and copiously with water.

In the case of reaction after contact with the product (cutaneous eruption), seek medical advice (show the label when possible). Swelling of the face, the lips and the eyes or respiratory difficulties are more serious symptoms, seek medical advice immediately.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Interactions with other medicaments : The bactericidal effect of amoxicillin is neutralized by simultaneous use of molecule with bacteriostatic action (macrolides, sulfonamides and tetracyclines).

Statement on usage during pregnancy and lactation: Laboratory studies have not produced any evidence of teratogenic, embryotoxic nor peri or post-birth effect of amoxicillin. As no studies have been carried out in target species during pregnancy, use in such case only according to the risk/benefit assessment made by the responsible veterinarian.

Adverse Effects: Penicillin and cephalosporins may cause hypersensitivity reactions unrelated to dose. Allergic reactions (cutaneous reactions, anaphylactic shock) can be occasionally severe. No adverse reaction was registered during clinical studies carried out with veterinary medicinal product itself.

Overdose: During experimental studies, the veterinary medicinal product has shown a good tolerance. No local or systemic toxicity was observed at the therapeutic dose and at twice this dose. No adverse effect has been noticed at 5-fold the therapeutic dose, except for a limited numbers of animals, a slight local reaction at the injection site that can be persistent until 4 days after administration, reversible without treatment and without any consequence for the animal.

Incompatibilities : None known

Storage Conditions: Do not store above 25°C.

Withdrawal Period:

Meat and offal : 46 days

Milk : 5 days

Packing: 100ml, 250ml and 500ml vial

FOR VETERINARY USE ONLY

Manufactured by:



DOPHARMA FRANCE, 23 rue du Prieuré, Saint Herblon, 44150 Vair sur Loire, France

Registration holder and repacker:



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LABEL CODE:	VERSION	COLORS
<p>PRODUCT: COFAMOX 15 L.A SUSPENSION FOR INJECTION</p> <p>PACK SIZE: 100 ML, 250 ML and 500 ML</p> <p>COUNTRY: MY</p> <p>DIMENSIONS: cm = 10 x 14</p>	<p>VERSION: 3</p> <p>MMM/YY: XXX</p>	<p>BLACK</p> <p>! Please use the official PANTONE® (P) matching system for accurate colour representation.</p>

Marketing approval:	Regulatory approval:	GMP approval:
<p>COMPLETE NAME:</p> <p>DATE:</p> <p>SIGNATURE:</p>	<p>COMPLETE NAME:</p> <p>DATE:</p> <p>SIGNATURE:</p>	<p>COMPLETE NAME:</p> <p>DATE:</p> <p>SIGNATURE:</p>