PACKAGE LEAFLET

PACKAGE LEAFLET FOR
Vetrimoxin L.A. 150 mg/ml suspension for injection for cattle and pigs [AT] [DE] [DK] [FI] [IS] [NL] [UK]
Longocilline 150 mg/ml suspension for injection for cattle and pigs [IE]
Vetrimoxin vet., 150 mg/ml suspension for injection for cattle and pigs [SE]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Manufacturer responsible for batch release:
Ceva Santé Animale
10, av. de La Ballastière
33500 Libourne
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetrimoxin L.A. 150 mg/ml suspension for injection for cattle and pigs [AT] [DE] [DK] [FI] [IS] [NL] [UK]
Longocilline 150 mg/ml suspension for injection for cattle and pigs [IE]
Vetrimoxin vet., 150 mg/ml suspension for injection for cattle and pigs [SE]
Amoxicillin (as trihydrate)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Suspension for injection.
Cream-beige suspension.

1 ml contains 150 mg amoxicillin (as trihydrate)

4. INDICATION

In cattle:
Treatment of respiratory infections caused by *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to amoxicillin.
In pigs:
Treatment of respiratory infections caused by *Pasteurella multocida* susceptible to amoxicillin.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to penicillins cephalosporins or to any of the excipients.
Do not use in cases of severe renal dysfunction with anuria and oliguria.
Do not use in case of infection with beta-lactamase-producing bacteria.
Do not use in rabbits, hares, hamsters, guinea pigs or other small herbivores.
Do not administer to Equidae, because amoxicillin – like all aminopenicillins – may adversely affect the bacterial flora of the caecum.

6. ADVERSE REACTIONS

Allergic reactions, varying in severity from a light skin reaction such as urticaria to anaphylactic shock.
In rare cases local irritation may occur due to the injection of amoxicillin. The frequency of this adverse reaction may be decreased by reducing the volume of injection per injection site (see section "Dosage for each species, route and method of administration"). The irritation is always of low intensity and recedes spontaneously and quickly.
In the case of allergic reactions, treatment should be discontinued and a symptomatic treatment should be initiated.
If you notice any serious effects or any other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and pigs

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Intramuscular use.
Shake well before use.

15 mg amoxicillin per kg bodyweight corresponding to 1 ml of the veterinary medicinal product per 10 kg.
Administration should be repeated after 48 hours.
To ensure a correct dosage and to avoid underdosing, body weight should be determined as accurately as possible.
In cattle, do not administer more than 20 ml of the veterinary medicinal product per injection site.
In pigs, do not administer more than 6 ml of the veterinary medicinal product per injection site.
A separate injection site should be used for each administration.
As with other injectable preparations normal aseptic precautions should be observed.
If no distinct clinical response is seen after the second treatment, a check of the diagnosis and eventually a change of treatment are required.
Do not broach the vial more than 10 times: if necessary, use automatic syringes.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Cattle:
Meat and offal: 18 days
Milk: 3 days
Pigs:
Meat and offal: 20 days

11. SPECIAL STORAGE CONDITIONS

Keep out of the sight and reach of children.
Do not refrigerate.
Protect from frost.

Keep the vial in the outer carton in order to protect from light.
Do not use his veterinary medicinal product after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.
Shelf-life after first broaching the bottle: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species
None.

Special precautions for use in animals
The choice of using amoxicillin should be based on bacterial susceptibility testing and take into account official, national and regional antimicrobial policies.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin and may decrease the effectiveness of treatment with amoxicillin due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillin and cephalosporin may cause an allergic reaction following accidental injection, inhalation or absorption via the skin, which may be life threatening. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Avoid direct contact of the veterinary medicinal product with the skin or the mucosae.
Handle the product with great care to avoid exposure.
Wear gloves and wash hands after use of the veterinary medicinal product.
In case of contact with the skin or eyes, wash immediately with water.
Do not smoke, eat or drink during use of the product.
If you develop symptoms following exposure, such as a skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Use during pregnancy, lactation or lay
Laboratory studies in rats and rabbits have not produced any evidence of harmful or toxic effect to the foetus or the mother (sow or cow). However, the tolerance of the medicinal product in cattle and pigs during pregnancy and lactation was not investigated. In these cases, use only in accordance with the benefit/risk assessment by the responsible veterinarian.

Interactions
Do not use with antibiotics, which inhibit bacterial protein synthesis and can produce a contrasting action to the bactericidal effect of penicillins.

Overdose
Amoxicillin has a wide safety margin.

Incompatibilities
Due to the lack of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pharmacodynamic properties

This product is a broad-spectrum antibiotic efficient to non β-lactamase producing Gram-positive and Gram-negative bacteria.

Pack sizes

- 100 ml
- 12 x 100 ml
- 250 ml
- 12 x 250 ml

Not all pack sizes may be marketed.