LABELLING "LABEL"

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

Marketing authorisation holder
Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

Manufacturer responsible for batch release:

laboratoires Biove 3 rue de lorraine 62510 Arques France	Ceva Santé Animale 200 Avenue de Mayenne Zone Industrielle des Touches 53000 LAVAL France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxival 500 mg/g oral powder for pigs and chickens
Amoxival Vet (DK)
Amoxicillin trihydrate

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

Each gram contains
Active substance:
Amoxicillin500.00 mg
(as amoxicillin trihydrate 574.00 mg)

Oral powder
White or almost white powder.

4. INDICATION(S)

Pigs (after weaning):
Treatment of swine pleuropneumonia due to *Actinobacillus pleuropneumoniae* (susceptible to amoxicillin).

Broiler chickens:
Prevention at the group level, when disease is present, of respiratory infections caused by *Escherichia coli* (susceptible to amoxicillin).

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to penicillins or other substances of the ß-lactam group.

Do not use in animals with serious kidney malfunction including anuria and oliguria.
Do not use in presence of β - lactamase producing bacteria.
Do not use in lagomorphs and rodents such as rabbits, guinea pigs, hamsters or gerbils.
Do not use in ruminants or horses.

6. ADVERSE REACTIONS

Penicillins and cephalosporins may cause hypersensitivity following administration. Allergic reactions to these substances may occasionally be serious.

If you notice any serious effects or other effects not mentioned in this label, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (pigs after weaning) and chickens (broilers)

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

In drinking water use / in feed use.

Pigs
20 mg of amoxicillin (as trihydrate) per kg body weight daily (i.e. 400 mg of the product per 10 kg body weight per day), administered for 5 consecutive days orally in liquid feed.

Chicken
20 mg of amoxicillin (as trihydrate) per kg body weight daily (i.e. 400 mg of the product per 10 kg body weight and per day) administered for 5 consecutive days in drinking water.

The required amount of product should be weighed as accurately as possible using suitably calibrated weighing equipment.

Body weight should be determined as accurately as possible to avoid underdosing.

The intake of medicated water or liquid depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted accordingly.

9. ADVICE ON CORRECT ADMINISTRATION

Recommendation for the pre-dilution:

- Add the necessary quantity of water in the container.
- Add then the product while stirring up the solution.
- Prepare the solution in ambient temperature (20°C – 25°C).
- Prepare the solution with fresh tap water (pH 5-9 / 20°C) immediately before use.

For a 20°C solution, respect a limit of concentration of 20g of product per liter of drinking water (equivalent to 10g of amoxicillin /L of water).

Take measures to avoid producing dust when incorporating the product into water

In drinking water: the stock solution is either mixed in the drinking water tank or used with a dosing pump. Turn off the water supply to the tank until all the medicated solution is consumed.
When using a proportionner, adjust the pump between 2 to 5% and adapt the volume of preparation accordingly. Do not set up the dosing pump below 2%.
Preparation of medicated water should provide an amount to be consumed within the next 12 hours. Any unused medicated water should be discarded after 12 hours, and freshly medicated water for the next 12 hours should be prepared.

In liquid feed: the pre-diluted solution must be mixed in the liquid feed until homogenous. The liquid feed should be continuously mixed during the preparation and the distribution to the animals.
Preparation of medicated liquid feed should provide an amount to be consumed within the next 3 hours. Any unused medicated liquid feed should be discarded after 3 hours, and freshly medicated liquid feed for the next 3 hours should be prepared.

10. WITHDRAWAL PERIOD

Meat and offal
Pigs: 14 days
Chicken: 1 day
Eggs: Not authorised for use in birds laying eggs for human consumption. Not to be used for at least 4 weeks before coming into lay.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

Shelf life after first opening the immediate packaging: 1 year
Shelf life after dilution in water: 12 hours
Shelf life after incorporation in liquid feed: 3 hours

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Once opened use by

12. SPECIAL WARNING(S)

Special precautions for use in animals:
The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of feed/ water animals should be treated parenterally.

Use of the product should be based on susceptibility testing of the bacteria isolated from animals. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Inappropriate use of the product may increase the prevalence of bacteria resistant to amoxicillin, other penicillins and may decrease its effectiveness..

Narrow spectrum antibacterial therapy should be used for first line treatment where susceptibility testing suggests the likely efficay of this approach.

Consideration should be given to improvement of management practice on the farm, mainly in hygiene management and ventilation avoiding stress conditions.

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 reactions to cephalosporins and *vice versa*. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Use inhalation protection and gloves during preparation.
Wash any exposed skin thoroughly.

Pregnancy, lactation:
Studies performed in Laboratory animals (rat, rabbit), did not show a teratogenic, embryotoxic or maternotoxic effect of amoxicillin. Safety of the product in the pregnant and lactating sows was not demonstrated. Use only accordingly to the benefit/risk assessment by the responsible veterinarian
Laying birds: Do not use in birds in lay

Interaction with other medicinal products and other forms of interaction:
The bactericidal effect of amoxicillin is neutralized by simultaneous use of pharmaceuticals with bacteriostatic mode of action.
Not to be used simultaneously with neomycin since it blocks the absorption of oral penicillins.

Overdose (symptoms, emergency procedures, antidotes):
No side effects were observed after administration at 5 times the recommended dosage.

Incompatibilities:
In the absence 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 MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Bags of 50 g - 100g - 500g - 1 kg - 2.5kg - 5kg
Box of 1 kg
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

MA number:

For animal treatment.

To be supplied only on veterinary prescription

BATCH NUMBER:

EXPIRY DATE:

09 November 2016