PACKAGE LEAFLET:

Perlium Amoxival 100 mg/g Premix for Medicated Feeding Stuff for Pigs

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

Marketing authorisation holder:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France

GB only:
Ceva Salute Animale S.p.A
Via G Leopardi 2/c
42025 Cavriago
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Perlium Amoxival 100 mg/g Premix for Medicated Feeding Stuff for Pigs

Amoxicillin (as Amoxicillin trihydrate)

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

1 g Premix contains:
Active substance:
Amoxicillin (as Amoxicillin trihydrate)..... 100 mg

Beige granulated powder

4. INDICATION(S)

In pigs: Preventive treatment of respiratory diseases due to *Streptococcus suis*, limited to reducing mortality. The presence of the disease in the herd should be established before the preventive treatment.

5. CONTRADINDICATIONS

Do not use in animals with serious kidney (accompanied by anuria and oliguria) and/or liver failure.
Do not use in animals with known hypersensitivity to betalactamins.
The use of the product is contraindicated when a resistance to amoxicillin is known.
Do not use in the presence of β-lactamase producing bacteria.
Do not administer to rabbits, guinea-pigs, hamsters or gerbils.

6. ADVERSE REACTIONS

Gastrointestinal signs may sometimes be observed (diarrhea).
Penicillins may cause allergic reactions after the administration of the product. Allergic reactions to these substances may sometimes be severe (anaphylaxis).
If you notice any serious effects or other effects not mentioned in this labelling, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs.

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

Premix for medicated feeding stuff.

20 mg of amoxicillin /kg body weight by day for 5 consecutive days, by oral route in feed.

9. ADVICE ON CORRECT ADMINISTRATION

For a feed intake of 40 g/kg, this dose regimen corresponds to 500 ppm in medicated feed. In order to respect the dose regimen and to take into account the real food intake, the incorporation rate can be increased, which leads to a higher concentration in food.
The product can be incorporated in pelleted feed preconditioned with steam for up to 15 minutes at a temperature not exceeding 78°C.
Do not use in liquid feed.

10. WITHDRAWAL PERIOD(S)

Meat and offal : 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a dry place. Store below 25 °C
Keep the bag tightly closed in order to protect from moisture.

Do not use this veterinary medicinal product after the expiry date stated on the bag after EXP. This date refers to the last day of that month.

Shelf life after first opening: use immediately after first opening
Shelf life after incorporation into meal and pelleted feed: 3 months

12. SPECIAL WARNING(S)

Animals with reduced feed intake and/or disturbed general condition have to be treated parenterally.

Special precautions for use in animals
Animals with distinctive clinical signs of streptococcosis require individual treatment.
Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies.
Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to amoxicillin.
This drug premix is intended for the preparation of solid drug feed and cannot be used as is; the concentration of incorporation of the drug premix in solid feed must not be lower than 5 kg/ton.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
When feed is being prepared, avoid skin contact.
Whilst handling the product, wear a mask, coveralls, protective goggles and gloves at all times.
Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143.
To rule out any risk of ingestion it is recommended not to eat, or drink while using the product and to wash the hands after use.
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 reaction to these substances may occasionally be serious.
1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure taking all recommended precautions.
3. 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 in breathing are more serious symptoms and require urgent medical attention.

Interaction with other medicinal products and other forms of interaction
Do not administer together with bacteriostatic anti-infectious agents (tetracyclines, sulphonamids…).
Do not use simultaneously with neomycin as it prevents the absorption of oral penicillins.

Overdose (symptoms, emergency procedures, antidotes)
A part from allergic reactions, penicillins have minimal direct toxicity.
There is no antidote, in case of accidental overdosage, the treatment is symptomatic.

Pregnancy and lactation
Laboratory studies have not produced any evidence of teratogenic, embryotoxic or maternotoxic effects of amoxicillin. Nevertheless, no study was performed in the target species during pregnancy or lactation. Therefore, use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Incompatibilities
In absence of compatibility studies this product must not be mixed with other veterinary products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, 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 APPROVED

January 2023

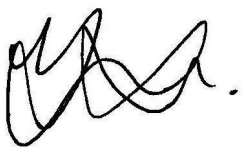
15. OTHER INFORMATION

ORAL ROUTE
FOR ANIMAL TREATMENT ONLY – TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION

PACKAGE SIZE
Bag of 10 kg
Bag of 25 kg
Not all pack sizes may be marketed

BATCH NUMBER

EXPIRY DATE



Approved: 17 January 2023