SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of premix contains :
Active substance
Amoxicillin (as Amoxicillin trihydrate) 100 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
Beige granulated powder

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

Do not use in animals with serious kidney (accompanied by anuria and oliguria) and/or liver failure.
Do not used 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.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

Premix for medicated feeding stuff.

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

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

A part from allergic reactions, penicillins have minimal direct toxicity.
There is no antidote, in case of accidental overdosage, the treatment is symptomatic.

4.11 Withdrawal period(s)

Meat and offal: 5 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use
ATC vet code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin is a semi-synthetic penicillin, derived from 6 APA (6-penicillinic acid). It is a slightly acid compound, slightly fat-soluble, stable in acid medium and can be administered by enteral or parenteral route.

Amoxicillin is a broad spectrum antibiotic with a bactericide effect primarily towards sensitive microorganisms. It causes deteriorations to the bacterial cell wall, leading to osmotic lysis of the cell.

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Streptococcus suis are usually susceptible to amoxicillin (MIC < 0.5 µg/ml).

MIC_{90} for *Streptococcus suis*
- 2007 - 2008 – France: 0.015µg/ml
- 2004 - 2005 – Germany: 0.06 µg/ml
- 1999 - 2001- Spain: ≤ 0.25 µg/ml

5.2 Pharmacokinetic particulars

After oral administration in feed, amoxicillin bioavailability is approximately 30 %. The fraction reaching the blood stream is metabolized to a slight extent. The metabolite identified in laboratory species is penicilloic acid that is rapidly eliminated in the urine. Amoxicillin is weakly bound to plasma proteins (about 20%) and is widely distributed in different organs.

After single oral administration of the product at dose level of 20mg/kg in pigs, mean Cmax corresponded to 2.93µg/mL, therefore almost 6 times the critical breakpoint for amoxicillin resistance in S. suis. The mean Tmax corresponded to 1.8 hour. The time when amoxicillin mean plasma concentrations were above the critical MIC (0.5µg/mL) was 6 hours, i.e., 25 % of the dosing interval.
Twelve hours after treatment, mean amoxicillin concentration was 0.159 µg/mL, i.e., still above the MIC90 values against S. suis (0.015µg/mL) observed in 2007-2008.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soya-bean oil, refined
Corn cob granules

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 1 year
Shelf life after first opening: use immediately after first opening
Shelf life after incorporation into meal and pelleted feed: 3 months

6.4 Special precautions for storage

Do not store above 25°C
Store in a dry place
Keep the bag tightly closed in order to protect from moisture

6.5 Nature and composition of immediate packaging

Low density polyethylene / paper / paper bag

Bag of 10 kg

Bag of 25 kg

Not all pack sizes may be marketed

6.6 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.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
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HP10 0HH
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8. MARKETING AUTHORISATION NUMBER

Vm 15052/5044

9. DATE OF FIRST AUTHORISATION

15 July 2010

10. DATE OF REVISION OF THE TEXT

May 2023

OTHER INFORMATION

To be supplied only on veterinary prescription.

Approved 26 May 2023