PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

25 kg bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

(Spain and Portugal)
APSAMIX AMOXICILINA 200 mg/g premix for feeding stuff for pigs

(Bulgaria, Cyprus and Greece)
APSAMIX AMOXICILLIN 200 mg/g premix for feeding stuff for pigs

2. COMPOSITION

Each g contains:

Active substance:
Amoxicillin (trihydrate).....200 mg

Excipients:

Qualitative composition of excipients and other constituents
Almond and hazelnut shell flour
Light liquid paraffin
Glycerol monostearate 40-55

Brown granular powder.

3. PACKAGE SIZE

25 kg

4. TARGET SPECIES

Pig (weaned piglet)

5. INDICATIONS FOR USE

Indications for use

Treatment and metaphylaxis of respiratory infections caused by Streptococcus suis susceptible to amoxicillin in pigs after weaning. The presence of the disease in the group must be established before the product is used.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypersensitivity to penicillins or other B-lactam antibiotics or to any of the excipients.

Do not administer to animals with severe renal dysfunction, including anuria or oliguria. Do not administer in the presence of ß-lactamase producing bacteria.

Do not administer to lagomorphs and rodents, such as rabbits, guinea pigs, hamsters or gerbils.

Do not administer to ruminants and horses.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

If an allergic reaction is observed, discontinue treatment.

Animals with reduced food intake and/or altered general condition should be treated parenterally.

Special precautions for safe use in the target species:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Inappropriate use of the veterinary medicinal product may increase the prevalence of penicillin-resistant bacteria.

Prolonged or repeated use should be avoided by improving on-farm management, mainly hygiene, ventilation and avoiding stressful conditions in the piglets.

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

Penicillins and cephalosporins may cause hypersensitivity (allergic) reactions after injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins can lead to cross-reactions with cephalosporins and vice versa. Allergic reactions to these substances can sometimes be severe.

Do not handle the veterinary medicinal product if you are allergic to penicillins and/or cephalosporins. Handle the veterinary medicinal product with care to avoid inhalation of dust, as well as contact with skin and eyes, taking all recommended precautions.

To avoid exposure during the preparation and administration of the medicated feed use personal protective equipment consisting of overalls, approved safety goggles, impervious gloves and a

disposable mask according to EN 149 or a non-disposable mask according to EN 140 with a filter according to EN 143.

Take appropriate measures to prevent the spread of dust during incorporation of the product into the feed.

Avoid contact with skin and eyes. In case of contact, wash thoroughly with plenty of clear water.

Do not smoke, eat or drink while handling the product.

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.

Wash hands after use.

Interactions with other medicinal products and other forms of interaction:

Do not use concurrently with neomycin as it blocks the absorption of oral penicillins.

Do not use in conjunction with antibiotics with a bacteriostatic mechanism of action (such as macrolides, sulphonamides and tetracyclines) as they may antagonise the bactericidal action of amoxicillin.

Overdose:

No adverse events have been observed at five times the recommended dose. In case of severe allergic reactions discontinue treatment and administer corticosteroids and adrenaline.

Special restrictions for use and special conditions for use:

This veterinary medicinal product is intended for the preparation of medicated feeding stuffs.

Administration under veterinary supervision or control.

Not to be used for prophylaxis.

Major incompatibilities:

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

8. ADVERSE EVENTS

Adverse events

Pig (weaned piglet)

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reactions (severity can range from simple hives to anaphylactic shock)[1]

[1]These reactions are dose independent. Medication should be discontinued and symptomatic treatment administered.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has

not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to <the marketing authorisation holder><the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system {national system details}.>

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Oral route. Administration in feed.

Administer 15 mg amoxicillin/kg bw/day (equivalent to 75 mg of the veterinary medicinal product/kg bw/day) for 15 days.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{75 mg veterinary medicinal product} \times \text{Peso medio de los animales a tratar (kg)}}{\text{Average daily feed consumption per animal (kg)}} = \text{mg veterinary medicinal product per kg of feed}$$

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of amoxicillin may need to be adjusted accordingly.

The use of suitably calibrated measuring equipment is recommended.

The feed incorporation rate is 2 kg/MT, for an intake of 40 g feed/kg b.w./day.

To ensure homogeneous incorporation of the premix into the feed when the drug is incorporated at a rate of less than 2 kg/Tm, it is recommended to prepare a premix beforehand. To do this, take the necessary quantity of APSAMIX AMOXICILLIN 200 mg/g and mix with 10 kg of feed for each ton of feed to be manufactured. Then, incorporate this preliminary mixture into the mixer and manufacture the medicated feed following the protocols established by the manufacturer.

During pelleting, the flour must not reach a temperature of more than 60°C. In case of pelleting at higher temperatures, the stability may be compromised.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 7 days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Store below 30ºC.
Protect from light.

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

EU/0/00/000/000

Pack sizes

Bag of 25 kg

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:

ANDRÉS PINTALUBA, S.A.
Polígono Industrial Agro-Reus
C/ Prudenci Bertrana nº 5
ES-43206 – REUS (Tarragona) España
Tel: +34 977317111

<Local representatives <and contact details to report suspected adverse reactions>:>

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

Република България
{Наименование}
<{Адрес}
BG {Град} {Пощенски код}>
Тел: + 359 {Телефонен номер}
<{E-mail}>

Ελλάδα
{Όνομα}
<{Διεύθυνση}
EL-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

Κύπρος
{Όνομα}
<{Διεύθυνση}
CY-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

Portugal
{Nome}
<{Morada}
PT-0000–000 {Cidade}>
Tel: + {Número de telefone}
<{E-mail}>

18. OTHER INFORMATION

Other information

Medicated premix for feeding stuffs.

Official provisions concerning the incorporation of medicated premixes in feed shall be taken into account.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once openeduse by…
Shelf life after first opening the immediate packaging: 1 month
Shelf life after incorporation into meal or pelleted feed: 3 months

21. BATCH NUMBER

Lot {number}