LABELLING AND PACKAGE INSERT

All the information required is conveyed on the container

OUTER LABELLING FOR:

RHEMOX PREMIX 100 mg/g premix for medicated feeding stuff for pigs

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

Marketing authorisation holder:
Industrial Veterinaria, S.A.
Esmeralda, 19
E-08950 Esplugues de Llobregat (Barcelona) Spain

Manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda, 19
E-08950 Esplugues de Llobregat (Barcelona) Spain

aniMedica Herstellungs GmbH
Pappelstr. 7 72160 Horb a. N
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

RHEMOX PREMIX 100 mg/g premix for medicated feeding stuff for pigs
Amoxicillin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Rhemox Premix is presented as light brown granules containing 100 mg of amoxicillin base as trihydrate per gram of product. Corncob is employed as carrier.

4. INDICATION(S)

Treatment and prevention of infectious processes caused by *Streptococcus suis* susceptible to amoxicillinin pigs after weaning.
The presence of disease in the herd should be established before treatment.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to penicillins or other antimicrobials of the beta-lactam group.
Do not use in the presence of beta-lactamase producing bacteria.
Do not use in animals with renal impairment.
Do not administer to rabbits, hamsters, gerbils and guinea pigs.

6. ADVERSE REACTIONS

Hypersensitivity reactions; severity can range from a simple rash to anaphylactic shock.
Gastrointestinal symptoms (vomiting, diarrhoea).
Suprainfections caused by non-sensitive germs after prolonged use.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform

your veterinary surgeon.

7. TARGET SPECIES

Pigs (after weaning)

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

In feed use

15 mg of amoxicillin/kg of b.w./day during 15 days.
This dose is equivalent to 0.15 g RHEMOX PREMIX/kg b.w./day

To calculate the dosage of RHEMOX PREMIX to be incorporated into feed:

g de RHEMOX PREMIX per kg of feed:

0.15 g RHEMOX PREMIX x Kg (body weight)/ Daily feed intake (Kg feed)

Considering that a pig consumes approximately 5% of its body weight per day, this dose corresponds to 300 mg of amoxicillin per Kg of feed which gives a rate of incorporation of 3.0 Kg/Ton (flour or granules).

The feed consumption will depend on the clinical condition of the animal. In order to obtain a correct dosage, the concentration of the antimicrobial agent should be adjusted taking into account the daily feed intake at the onset of treatment.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing

9. ADVICE ON CORRECT ADMINISTRATION

Mixing instructions:
To ensure a correct dispersion, the veterinary medicinal product should first be mixed to equal parts with feed before incorporation into the final mix.
Avoid contact with water.
The veterinary medicinal product can be incorporated into pelleted feed, preaconditioned at a temperature not greater than 85ºC.

10. WITHDRAWAL PERIOD

Meat and offal: 4 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25ºC. Store in a dry place.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf-life after first opening the container: 3 months.
Shelf-life after incorporation into meal o pelleted feed: 3 months.
After first opening, keep the container tightly closed.

EXP {month/year}

12. SPECIAL WARNING(S)

Special precautions for use in animals

Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies.

Long term or repeated use should be avoided by improving management practice and thorough cleansing and disinfection. Narrow spectrum antibacterial therapy 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 bacteria resistant to amoxicillin.

The intake of medication by animals can be altered as a consequence of illness. In case of insufficient intake of feed, animals should be treated by the parenteral route.

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

Avoid inhalation of dust and contact with skin.

When applying the product, wear gloves and a disposable half-mask respirator conforming to European Standard EN 140 with a filter to EN 143.

Penicillins may cause hypersensitivity (allergy) following inhalation, ingestion and 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.

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.

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

Wash hands after use.

Interaction with other medicinal products and other forms of interaction

Do not administer together with bacteriostatic anti-infectious agents (tetracyclines, sulphamides, spectinomycin, trimethoprim, chloramphenicol, macrolides and lincosamides)
Do not use simultaneously with neomycin as it blocks the absorption of oral penicillins.
Do not use with antibiotics which inhibit bacterial protein synthesis as they can antagonise the bactericide effect of penicillins, except for aminoglycoside antibiotics which are recommended for use with penicillins.

Overdose (symptoms, emergency procedures, antidotes)

No adverse reactions were showed at 3X the recommended dose (45 mg/kg) for 15 days and at dose levels but twice time the period treatment (30 days).
If allergic or anaphylactic reactions were appearing, the medication will be suspended and the veterinarian will be warned. The immediate administration of epinephrine, antihistamines and/or corticoids is considered to be a suitable therapy of emergency.

Incompatibilities

None known.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{<DD/MM/YYYY>}

15. OTHER INFORMATION

Veterinary medicinal product subject to prescription.
Administration by a veterinary surgeon or under their direct responsibility
PACKAGE SIZE
3 kg
24 kg
Not all pack sizes may be marketed

16. MARKETING AUTHORISATION NUMBER(S)

{number}

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}