ANNEX III LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - $\underline{\text{COMBINED LABEL}}$ AND PACKAGE LEAFLET

Outer labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rhemox Premix 100 mg/g premix for medicated feeding stuff for pigs

2. COMPOSITION

Each g contains:

Active substance:

Amoxicillin base 100 mg (as amoxicillin trihydrate 114.8 mg)

Excipients:

Qualitative composition of excipients and other constituents

Non-crystallising liquid sorbitol

Light liquid paraffin

Corncob

Light brown granules.

3. PACKAGE SIZE

3 kg 24 kg

4. TARGET SPECIES

Pig (after weaning)

5. INDICATIONS FOR USE

Indications for use

Treatment and metaphylaxis of infectious processes caused by *Streptococcus suis* susceptible to amoxicillin in pigs after weaning.

The presence of disease in the herd should be established before treatment.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypersensitivity to the active substance, other antimicrobials of the beta-lactam group or to any of the excipients.

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.

7. SPECIAL WARNINGS

Special warnings

Special precautions for safe use in the target species:

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:

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 veterinary medicinal product if you know you are sensitised or if you have been advised not to work with such preparations.

Avoid inhalation of dust and contact with skin.

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

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 veterinary medicinal product.

Wash hands after use.

Interactions 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:

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.

Special restrictions for use and special conditions for use:

This veterinary medicinal product is intended to be used for the preparation of medicated feed.

[Administration conditions: to be complemented nationally]

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 (after weaning):

Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reaction ¹ (e.g. urticarial rash and anaphylactic shock)
	Gastrointestinal signs (e.g. vomiting and diarrhoea) Opportunistic infection ²

¹severity can range from a simple rash to anaphylactic shock.

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 or 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 SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes 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 of the veterinary medicinal product/kg b.w./day

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. 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:

mg veterinary medicinal product average body weight (kg) mg veterinary medicinal /kg body weight day x of animals to be treated average daily feed consumption (kg/animal) = product per kg of feed

²suprainfections caused by non-sensitive germs after prolonged use.

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).

10. ADVICE ON CORRECT ADMINISTRATION

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, preconditioned at a temperature not greater than 85°C.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 4 days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.

Keep the container tightly closed.

Store in a dry place.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. 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

[Item to be completed by the marketing authorisation holder once the marketing authorisation has been granted]

Pack sizes:

3 kg bag

24 kg bag

Not all pack sizes may be marketed.

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:

Industrial Veterinaria, S.A.

Esmeralda, 19

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

Friulchem S.p.A.

Via San Marco 23

33099 Vivaro PN

Italy

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

To be completed nationally

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use by...

Shelf life after first opening the immediate packaging: 3 months

Shelf life after incorporation into meal or pelleted feed: 3 months

21. BATCH NUMBER

Lot {number}