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

Outer labelling

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each g contains:

Active substance:

Amoxicillin (as trihydrate) 100 mg

Excipients:

Qualitative composition of excipients and other constituents
Non-crystallising liquid sorbitol
Light liquid paraffin
Corncob

Light brown granules.

1. PACKAGE SIZE

3 kg.
24 kg.

2. TARGET SPECIES

Pigs (weaned piglets).

5. INDICATIONS FOR USE

Indications for use

Treatment of infections 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 orally to rabbits, guinea pigs or hamsters, given that amoxicillin, as all aminopenicillins, has an important effect on caecal bacteria.

Do not use in equidae, given that amoxillin, as all aminopenicillins, has an important effect on caecal

bacterial population.
Do not administer orally to animals with functional rumen.

7. SPECIAL WARNINGS

Special warnings
Special warnings:
The veterinary medicinal product is not effective against beta-lactamase producing organisms.
Cross-resistance has been shown between amoxicillin and other penicillins, in particular aminopenicillins in bacteria susceptible to amoxicillin. Use of the veterinary medicinal product/amoxicillin should be carefully considered when susceptibility testing has shown resistance to penicillins because its effectiveness may be reduced.
The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient feed uptake, animals should be treated parenterally using a suitable injectable veterinary medicinal product prescribed by the veterinarian.

Special precautions for safe use in the target species:
Use of the veterinary medicinal 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 veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to amoxicillin and may decrease the effectiveness of treatment with other penicillins, due to the potential for cross-resistance.
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.
The antimicrobial should not be used as part of herd health programmes.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause hypersensitivity reactions (allergy) after injection, inhalation, ingestion or 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 the 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, skin and eye contact.
Personal protective equipment consisting of gloves and a disposable half-mask respirator conforming to European Standard EN 140 with a filter to EN 143 should be worn when handling the veterinary medicinal product.
In case of contact, it is recommended to wash the area with plenty of water.
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 breathing difficulties 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…)
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:

Due to the broad safety margin, is practically impossible the poisoning by accidental overdose.
If allergic or anaphylactic reactions were appearing, the medication will be suspended and the veterinarian will be warned. The immediate administration of adrenaline, 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.

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

Pigs (weaned piglets):

Undetermined frequency (Cannot be estimated from the available data)	Hypersensitivity reaction[1] Gastrointestinal signs (e.g. vomiting and diarrhoea) Opportunistic infection[2]

[1] Severity can range from a simple rash to anaphylactic shock.

[2] Suprainfections caused by non-sensitive germs after prolonged use.

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 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. 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:

$$\frac{\text{mg veterinary medicinal product /kg body weight day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily feed consumption (kg/animal)}} = \text{mg veterinary medicinal product per kg of feed}$$

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 Kg/Ton (flour or granules).

Treatment should continue for 15 days.

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.
The veterinary medicinal product can be incorporated into pelleted feed, preaconditioned at a temperature not greater than 85 ºC.

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 ºC.
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

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
{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details
Marketing authorisation holder and manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda, 19
08950 Esplugues de Llobregat (Barcelona) Spain

Manufacturer responsible for batch release:
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}