INMEDIATE AND PACKAGE LEAFLET

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

Marketing authorisation holder and manufacturer

LABORATORIOS CALIER, S.A.

C/ Barcelonès, 26. Pla del Ramassà.

08520 LES FRANQUESES DEL VALLÈS.

BARCELONA. SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZOOBIOTIC 5% PREMIX GLOBULIT® (HU, IT,PL)
Amoxicillin trihydrate

ZOOBIOTIC GLOBULIT® 50 mg/g premix for medicated feeding stuff (ES, CZ, PT)
Amoxicillin trihydrate

Amoxicilline Calier 50 mg/g Premix Globulit® (FR)
Amoxicillin trihydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One gram of the veterinary medicinal product contains:

Active substance:

Amoxicillin (trihydrate).....50 mg

4. INDICATION(S)

Prevention of infections due to *Streptococcus suis* susceptible to amoxicilin after weaning. The presence of disease in the herd should be established before treatment.

5. CONTRAINDICATIONS

Do not administer to animals with a known hypersensitivity record to penicillins or other substances of the ß-lactam group. Do not administer to animals with serious kidney malfunction including anuria or oliguria.

Do not use in case of presence of ß-lactamases producing bacteria.

Do not use in lagomorphs and rodents such as rabbits, guinea pigs, hamster or gerbil.

Do not use in ruminants nor horses.

6. ADVERSE REACTIONS

Penicillins and cephalosporins may cause hypersensitivity following administration. Hypersensitive reactions are unrelated to dose. Allergic reactions (e.g. skin reaction, anaphylaxis) may occasionally occur and could occasionally be serious.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Porcine (weaned pigs)

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

In-feed use

The dose of amoxicillin is 15 mg/kg b.w/day during 15 consecutive days.
For a feed intake of 50 g/kg, this dose regimen corresponds to 300 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.

Posology of Zoobiotic 5 % Premix Globulit for medicated feeding stuff for pigs in feed can be established by the following formula:

mg Zoobiotic 5 % Premix Globulit for medicated feeding stuff for pigs /kg feed= (300 mg Zoobiotic 5 % Premix Globulit for medicated feeding stuff for pigs /kg b.w. / day) X (mean body weight of the animals to be treated (Kg)) / mean daily feed intake (Kg)

As a standard the incorporation rate in feed must be established in 6-8 Kg Zoobiotic 5% Premix Globulit® /Tn of feed. The incorporation rate of medicated premix in food should not be inferior to 5 kg/ton.

Granulation of medicated feed has to be carried out at a temperature not exceeding 55º C.

9. ADVICE ON CORRECT ADMINISTRATION

In case of any infective process, a bacteriological confirmation of the diagnostic is recommended, as well as a sensitivity test of bacteria causing the process.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

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

10. WITHDRAWAL PERIOD

Meat and offals: 7 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children

Do not store above 30°C

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

Once the container has been opened, the product should be immediately used.

Do not used after the expiry date which is stated after EXP.

12. SPECIAL WARNINGS

In case of the occurrence of allergic reaction, the treatment should be withdrawn.

Use of this product should be based on susceptibility testing and take into account official and local antimicrobial policies. 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 product may increase the prevalence of bacteria resistant to amoxicillin. The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of feed animals should be treated parenterally. Consideration should be given to improvement of management practice on the farm, mainly in hygiene management, ventilation and piglet and management avoiding stress conditions.

Penicillins and cephalosporins can cause hipersensitivity reaction (allergy) after injection, inhalation, ingestion or skin contact. Crossed hipersensitivity reactions between penicillins and cephalosporins are observed.

- Do not handle the product if you are allergic to penicillins and/or cephalosporins.

- Handle the product with care to avoid dust inhalation, as well as contact with skin and eyes during incorporation of premix into feed, by taking specific precautions:
    - Take the appropriate measures to avoid dust dissemination during the incorporation of the premix into feed.
    - Wear a dust mask (in compliance with EN140FFP1), gloves, overalls, and approved safety glasses.
    - Avoid contact with skin and eyes. Rinse thoroughly with water in case of exposure.
    - Do not smoke, eat, or drink when handling the product.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the present warning to the doctor. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

The bactericidal effect of amoxicillin is neutralized by simultaneous use of pharmaceuticals with bacteriostatic mode of action (such as macrolides, sulfonamides and tetracyclines)It should not be used simultaneously with neomycin since it blocks the absorption of oral penicillins.

No secondary effects have been detected at five times the dosage level. In case of severe allergic reactions the medication should be discontinued and corticoids and adrenaline should be administered. In the other cases, apply symptomatic treatment.

Incompatibilities:

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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15. OTHER INFORMATION

Keep out of the reach and sight of children

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

Reg No.

Bags of 25 kg

For animal treatment only. To be supplied only on veterinary prescription

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

Batch:

EXP:(month/year)