LABELLING AND PACKAGE LEAFLET

PACKAGE LEAFLET (Label)

Vetrimoxin 50mg/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

Manufacturer responsible for the batch release:
Ceva Salute Animale S.p.a – Via Leopardi, 2/c – 42025 Cavriago (RE) – Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetrimoxin 50mg/g Premix for medicated feeding stuff for pigs
Amoxicillin trihydrate

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

Each g contains: 50 mg Amoxicillin (as trihydrate)

VETRIMOXIN 50mg/g is a granular powder premix for medicated feeding stuff containing 50mg/g amoxicillin (as trihydrate). The carrier of the premix is the wheat starch

4. INDICATION(S)

In weaned pigs: in herds where infection has been confirmed treatment of infections caused by *Streptococcus Suis* susceptible to amoxicillin.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to amoxicillin or other β-lactam.
Do not use by oral route to rabbits, guinea pig, hamsters and horses since the amoxicillin, like all the aminopenicillins, has an important action on caecum microflora population.
Do not use by oral route to animals with functional rumen
Do not use where resistance to other β-lactam is known to occur

6. ADVERSE REACTIONS

Reactions of sensitization whose gravity can vary from a simple urticaria to an anaphylactic shock.
Supra infections by non-sensible germs after its prolonged use.
Occasionally can produce haematology disturbances and colitis.

If you notice any serious effect or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (weaned pigs)

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

For oral administration only after incorporation in feed.
In-feed use at the final dose 15 mg amoxicillin/ kg b.w./ day, during 14 consecutive days.
In the case of an altered feed intake (clinical status, weight class, age, environment), adjust the incorporation rate in order to guarantee an intake of 15 mg amoxicillin/kg b.w./day.
According to the recommended dose, the number and animals weight to be treated, the exact dose of medicinal product to be incorporated in the feed should be calculated using the following formula:

$$\frac{\text{0.3 g of medicinal product } \mathbf{X} \text{ Average bodyweight of treated animals (kg) / day}}{\text{Daily feed intake (kg)}} = \text{kg Vetrimoxin/ton of feed}$$

During the granulation, mixture should not reach a temperature above 60ºC.

9. ADVICE ON CORRECT ADMINISTRATION

Body weight should be evaluated accurately to avoid underdosing.

Feed intake depends on the clinical condition of the animal, thus the concentration in the feed should be adjusted to assure the correct dosage. Mix well to ensure homogeneous distribution.
The medicated feed should be the only source of feed during the 14 days of treatment, which represents the maximum period of treatment with the product.

10. WITHDRAWAL PERIOD

Meat and offal**:** 3 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf life after first opening the container: 3 months
Shelf life after incorporation into meal or pelleted feed: 3 months

12. SPECIAL WARNING(S)

Interaction
Do not use simultaneously with neomycin since it blocks the absorption of oral penicillins.
Do not use jointly with antibiotics that inhibit the bacterial protein synthesis since they can antagonize the bactericidal action of penicillins.

Overdose
Amoxicillin has an ample safety margin
In case of appearing intense allergic reactions stop the treatment and administer corticoids and adrenalin.
In other cases administer symptomatic treatment

Special precautions for use in animals
The dosage of the product should be strictly followed in animals with renal insufficiency.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.
The uptake of medication by animals can be altered as a consequence of illness. In case of severely reduced feed intake animals should be treated parenterally
Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to Amoxicillin and other β-lactam.
The prolonged or repeated use should be avoided by e.g. improving management practices, proper cleaning and disinfection. Particular attention should be paid to improvement of farming practices to avoid any stress condition.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillins and cephalosporins may cause hypersensitivity following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
People with known hypersensitivity should avoid contact with the veterinary medicinal product.
In case of development of a skin rash following exposure, seek medical advice.
Handle the product with great care to avoid exposure, taking all recommendations.
Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.
Avoid direct contact with the product.
Personal protective equipment consisting of protective goggles, impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN 149) should be worn when handling the veterinary medicinal product.
In case of accidental contact washed affected area abundantly with clear water.
Do not smoke, eat or drink while handling the product.
Wash hands immediately after handling the product.

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 MATERIAL, 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

15. OTHER INFORMATION

Pack size:
Bags of 10 and 25kg
Not all pack sizes may be marketed.

For Animal treatment only
To be supply only on veterinary prescription.
Administration by a veterinary surgeon or under their direct responsibility.

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

MA number:
Lot:
Exp: