I.B.2. LABEL/PACKAGE LEAFLET

Maymoxi 100 g/kg Premezcla medicamentosa (ES)
Maymoxi 100g/kg Premiscela per suini (IT)
Maymoxi 10 Pré-mistura medicamentosa para suínos (PT)

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 responsible for batch release:
Laboratorios Maymó, S.A.
Vía Augusta, 302.
08017 Barcelona (Spain)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maymoxi 100 g/kg Premezcla medicamentosa (ES)
Maymoxi 100g/kg Premiscela per suini (IT)
Maymoxi 10 Pré-mistura medicamentosa para suínos (PT)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each kg of product contains:

Amoxicillin (trihydrate) ..... 100 g

4. INDICATIONS

Prevention and treatment of respiratory infections caused by *Streptococcus suis* sensible to amoxicillin in weaned piglets.
The presence of the disease in the herd should be established before the preventive treatment.

5. CONTRAINDICATIONS

Do not administer to animals with history of hypersensibility to penicillins or cephalosporins or to any of the excipients.Do not administer in case resistance to penicillins or cephalosporins occurs.
Do not administer to rabbits, guinea pigs and hamsters, due to the fact that amoxicillin, as well as all other aminopenicillins, has an important action on the cecal bacterial population.
Do not administer to equine, due to the fact that amoxicillin, as well as all other aminopenicillins, has an important action on the cecal bacterial population.

6. ADVERSE REACTIONS

The adverse reactions described for penicillins are: hypersensibility reactions, with variable seriousness from a simple urticaria to an anaphylactic shock. Intestinal symptomatology (vomiting, diarrhoea).

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

7. TARGET SPECIES

Porcine (weaned piglets).

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Oral administration mixed with feed.
Administer 20 mg of amoxicillin/kg of bw/day (equivalent to 2 g of Maymoxi 10 Premix*/10 bw/day) during 15 days.

Due to the administration form and to the fact that the water and feed consumption depend on the clinical condition of the animal, in order to assure a correct dosing, the antimicrobial concentration will be adjusted taking into account the daily consumption of feed and water. For example, the following formula may be used to calculate the medicinal product dose:

$$\frac{\text{200 mg “Maymoxi 10 Premix*” per kg bw./day} \times \text{Mean weight of animals to be treated (kg)}}{\text{Mean daily feed ingestion by animal (kg)}} = \text{mg “Maymoxi 10 Premix*”/kg of feed}$$

The standard rate of addition to feed would be 4 kg of Maymoxi 10 Premix* per tonne of feed.
Temperature, pressure and humidity conditions to which the granulated feed medicated with the premix, may be subjected, are that common for the granulation: use of humid head at 150ºC, at a steam pressure of 3.6 bar for 3 minutes and a mechanical pressure of 10 bars. These conditions inside the room provide a maximum temperature of 65-70ºC, 15% of humidity and 10 bars of pressure.

9. ADVICE ON CORRECT ADMINISTRATION

Body weight of treated animals should be determined accurately to avoid underdosing.

10. WITHDRAWAL PERIOD

Meat and offal: 8 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.
Shelf life after first opening the container: 6 months
Shelf life after incorporation into medicated feed: 3 months

12. SPECIAL WARNINGS

Special warnings for each target species:
The ingestion of medication by the animal may be altered due to the illness.
In case of an insufficient feed ingestion, the animals will be treated parenterally.
Narrow spectrum antibacterial therapy should be used for first line treatment where susceptibility testing suggest the likely efficacy of this approach.
Inappropriate use of the product may increase the prevalence of bacteria resistant to penicillins.

Special precautions for use in animals:
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may produce hypersensibility reactions (allergy) after the injection, inhalation, ingestion or skin contact. Cross hypersensibility reactions are observed between cephalosporins and penicillins.
Do not handle the product if you are allergic to penicillins and/or cephalosporins. Handle with care to avoid contact during its addition to feed, as well during the administration of medicinal feed to the animals, taking specific precautions:

– Avoid dust dissemination during the addition of the product to feed.
– Wear an anti-dust mask (conforming to European Standard EN 140FFP1), gloves, working dress and approved safety glasses.
– Wash hands after using the product.
– If an accidental exposure of skin or eyes takes place, wash immediately with abundant water.
– Do not smoke, eat or drink while handling the product.

If symptoms appear after exposure, as cutaneous eruption, consult a doctor and show these warnings. Face, lip or eye inflammation or respiratory difficulty, are more serious signs, which require urgent medical attention.

Use during pregnancy, lactation or lay:
Not applicable.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with neomycin, since it blocks the absorption of oral penicillins.
Do not use together with antibiotics which inhibit bacterial protein synthesis, since they may antagonise the bactericidal action of penicillins.

Overdose (symptoms, emergency procedures, antidotes):
The administration of five times the therapeutic dose during 30 consecutive days did not produce any adverse reaction.
In case of intense allergic reactions, the treatment must be discontinued and corticoids and antihistaminics administered. In other cases administer 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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD month YYYY

15. OTHER INFORMATION

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

MARKETING AUTHORISATION NUMBER
ES: 1748 ESP
IT: 104026/012
PT: 092/01/08RFVPT

PACKAGE SIZE
25 kg

EXPIRY DATE
EXP {month/year}

MANUFACTURER'S BATCH NUMBER
Lot{number}