PACKAGE LEAFLET / LABEL FOR:

NIPOXYME 22.500.000 IU/g POWDER FOR USE IN DRINKING WATER

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

Marketing authorisation holder: Andersen S.A. Avda. de la Llana, 123 08191 Rubí (Spain).

Manufacturer responsible for batch release: Laboratorios Maymó S.A. Polígono Industrial Can Pelegrí C/ Ferro, 9. 08755 Castellbisbal (SPAIN)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nipoxyme 22.500.000 IU/g powder for use in drinking water.

Colistin sulphate.

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each g contains: Colistin (as sulphate) 22.500.000 IU

4. INDICATIONS

Treatment and metaphylaxis of the enteric infections caused by non-invasive E.coli susceptible to colistin.The presence of the disease in the herd should be established before metaphylactic treatment.

5. CONTRAINDICATIONS

Do not use in animals with kidney failure. Do not use in case of hypersensitivity to polypeptide antibiotics.

Do not use in horses, particularly in foals, since colistin, due to a shift in the gastrointestinal microflora balance could lead to the development of antimicrobial associated colitis (Colitis X), typically associated with *Clostridium difficile*, which may be fatal.

6. ADVERSE REACTIONS

None. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pig.

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

For administration in drinking water.

The recommended dose is 150.000 IUde colistin/kg bw/day during 5-7 days (equivalent to 5.8 mg of product/kg bw/day) to add to drinking water.

The quantity of product to add to the water can be calculated using the following formula:

$$\text{Quantity (mg) of product / l drinking water} = \frac{\text{5.8 mg of product/kg bw/day} \times \text{mean weight of the animal (kg)}}{\text{Mean daily consumption (litres)}}$$

9. ADVICE ON CORRECT ADMINISTRATION

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

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

The medicated water should be the only source of drinking water. Medicated drinking water should be refreshed or replaced every 24 hours.

10. WITHDRAWAL PERIOD

Meat and offal: 1 day.

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 of the immediate packaging: 14 days.

Shelf-life after dilution according to directions: 24 hours.

12. SPECIAL WARNINGS

Special precautions for use in animals:

Do not use colistin as a substitute for good management practices.

Colistin is a last resort drug in human medicine for treatment of infections caused by certain multi-drug resistant bacteria. In order to minimise any potential risk associated with widespread use of colistin, its use should be limited to treatment or treatment and metaphylaxis of diseases, and should not be used for prophylaxis.

Whenever possible, colistin should only be used based on susceptibility testing.

Use of the product deviating from the instructions given in the SPC may lead to treatment failures and increase the prevalence of bacteria resistant to colistin.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Individuals with known hypersensitivity to the colistin (sulphate) should avoid contact with the veterinary medicinal product. Personal protective equipment consisting of rubber gloves should be worn when handling the veterinary medicinal product. Avoid the contact with the eyes and skin. In the case of accidental contact, rinse immediately with plenty of water, seek medical advice and show the package leaflet or the label to the physician. Wash handsafter using the product. Keep the container well closed and away from the light, and always keep the product label for identification purposes. Use the product in places with suitable ventilation. Do not smoke, eat or drink while handling the product. If it appears symptoms after the contact, like dermal eruption seek medical advice and present these warnings. The swelling of the face, lips either eyes or respiratory difficulty are serious signs that require urgent medical attention.

Pregnancy and lactation:

The use is not recommended during pregnancy and lactation as colistin safety during these periods has not been studied in the target species.

Interaction with other medicinal products and other forms of interaction:

After oral administration of colistin sulphate interaction with anaesthetics and myorelaxants may not be excluded in individual cases. The effects of colistin sulphate may be antagonized by binary cations (iron, calcium, magnesium) and by unsaturated fatty acids".

Overdose (symptoms, emergency procedures, antidotes):

In the event of overdose, transient digestive problems such as soft stools of tympanites may appear. Signs of neurotoxicity and nephrotoxicity may appear.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. This product must not be mixed with divalent cations (calcium, magnesium, manganese) and unsaturated fatty acids.

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 or pharmacist 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

15. OTHER INFORMATION

For animal treatment only – to be supplied on veterinary prescription.

Administration by a veterinary surgeon or under their direct responsibility.

Pack sizes: fold-up cardboard box with an inner lining of aluminium/low-density polyethylene of 250 g, 500 g, 1 kg.

A 250g bag of polyester/aluminium /low-density polyethylene.

Marketing authorization nº:

Lot:

EXP: