

1.B.2 LABELLING AND PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

NEOMAY 100 000 IU/g

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

Laboratorios Maymó, S.A.
Vía Augusta, 302
08017, Barcelona (Spain).

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neomay 100 000 IU/g
Neomycin (as neomycin sulphate)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each g contains:

Neomycin (as neomycin sulphate) 100 000 IU
Excipient, q.s. 1 g

4. INDICATIONS

Cattle (calves): colibacillosis and salmonellosis.

Pig: colibacillosis, edema disease, salmonellosis and haemorrhagic dysentery.

Poultry (layer hen, chickens and turkeys for meat production): treatment of gastrointestinal infections caused by microorganisms sensitive to neomycin.

Rabbits: treatment and metaphylaxis of gastrointestinal infections caused by *E. coli* strains sensitive to neomycin.

The presence of the disease in the herd should be established before treatment.

5. CONTRAINDICATIONS

Do not use in cattle with functional rumen.

Do not use in dehydrated animals with renal failure or respiratory depression

Do not use in case of hypersensitivity to the active substance, to aminoglycosides or to the excipient.

6. ADVERSE REACTIONS

A long-term use can cause intestinal malabsorption and dysbacteriosis syndrome.

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

7. TARGET SPECIES

Cattle (calves), pig, poultry (layer hen, chickens and turkeys for meat production) and rabbits.

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

In feed use:

- Calves, pig and poultry: 3.200-6.400 IU of neomycin/kg bw/day (equivalent to 32-64 mg of product/kg bw/day) during 3- 5 consecutive days.
- Rabbits: 35.000 IU of neomycin/kg bw/day (equivalent to 350 mg of product /kg bw/day during 7 consecutive days.
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For all the species:

The intake of feed depends on the clinical condition of the animals and the season. To ensure a correct dosage the concentration of neomycin sulphate in feed, it shall be adjusted taking into account the daily consumption. The following formula may be used:

$$\text{Kg of premix per ton of feed/day} = \frac{\text{Dose /Iu/kg bw) x bw (kg)}}{\text{Daily intake (kg) x Dose of Premix (IU/g)}}$$

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

The medicated feed should be the only feed supply to the animals during the treatment period.

Make a predilution to incorporate in the feed in not less than 2 kg / ton.

The granulation process for rabbit feed is usually done at a temperature in the conditioner 80 and with a vapor pressure of 2.5 atmospheres.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable

10. WITHDRAWAL PERIOD

Meat and offal:

Cattle (calves): 30 days

Pig: 20 days

Poultry (turkeys for meat production): 14 days

Poultry (Chicken for meat production): 5 days

Rabbits: zero days

Eggs: Poultry (laying hens): 14 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 meal or pelleted feed: 3 months

12. SPECIAL WARNINGS

Special warnings for each target species:

None

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.

Food intake by animals can be altered as a result of the disease. In animals with lack of appetite or reduced consumption, administering a parenteral alternative treatment.

Official, national and regional antimicrobial policies should be taken into account when the product is used.

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

People with known hypersensitivity to neomycin should avoid contact with the veterinary medicinal product.

Avoid direct contact with skin and mucous membranes while mixing the veterinary medicinal product and handling the medicated feed. If symptoms such as rash appear after exposure, seek medical advice and show the package leaflet or the label to the physician. Swelling of face, lips or eyes, and difficulty breathing are serious signs that require urgent medical attention.

The following specific precautions should be taken:

- Take the appropriate measures to avoid the spread of dust during the incorporation of the veterinary medicinal product in the feed.
- Personal protective equipment consisting of overalls, gloves, masks and safety glasses should be worn when handling the veterinary medicinal product.
- In case of accidental spillage onto skin or mucous membranes, rinse the affected area with plenty of water.
- Wash hands after use.
- Do not smoke, eat or drink while handling the veterinary medicinal product

Pregnancy, lactation or lay:

Laboratory studies in rats have not demonstrated any evidence of teratogenic effects.

The safety of the veterinary medicinal product has not been demonstrated during pregnancy and lactation in the target species.

The use will be accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not use with general anaesthetics, muscle neuro-blocking, antidiuretics and other aminoglycosides.

Overdose (symptoms, emergency procedures, antidotes):

Nephrotoxic and/or ototoxic effects may occur in case of an overdose and during extended periods.

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

MM/YYYY

15. OTHER INFORMATION

For animal treatment only

Environmental properties:

Neomycin is persistent in soil.

Manure originated in rabbit treated with this veterinary medicinal product applied to agricultural land may cause toxicity to terrestrial plants and earthworms.

Package size

25 kg

Expiry date

EXP {month/year}

Marketing Authorisation Number
XXXXX

Manufacturer's batch number
Lot {number}