1.B.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
NEOMAY 100 000 IU/g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each g contains:
Active substance:
Neomycin (as neomycin sulphate) ..... 100 000 IU
Excipients:
Wheat bran
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. CLINICAL PARTICULARS
4.1 Target species
Cattle (calves), pig, poultry (layer hen, chickens and turkeys for meat production) and rabbits.

4.2 Indications for use, specifying the target species
Cattle (calves): colibacilosis and salmonellosis.
Pig: colibacilosis, 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 metaphilaxis of gastrointestinal infections caused by *E. coli* strains sensitive to neomycin.
The presence of the disease in the herd should be established before treatment.

4.3 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.

4.4 Special warnings for each target species
None

4.5 Special precautions for use
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 the 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

Other precautions
None.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during 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.

4.8 Interaction with other medicinal products and others

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

4.9 Amounts to be administered and administration route

In feed use:

- Calves, pigs and poultry: 3200-6400 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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
Nephrotoxic and/or ototoxic effects may occur in case of an overdose and during extended periods.

4.11 Withdrawal periods
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

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: intestinal anti-infectives, antibiotics.
ATCvet code: QA07AA01.

5.1 Pharmacodynamic properties
Neomycin is an antibiotic from the aminoglycoside family with bactericide activity. It acts by inhibiting the translation process of protein synthesis through interference with **the 30S ribosomal subunit** in sensitive organisms.
It is active against gram-negative aerobic microorganisms. Anaerobics microorganisms are resistant.

Neomycin **has** cross-resistance to other aminoglycosides. Resistance to aminoglycosides may be due to three different mechanisms: decreasing the intracellular accumulation of the antibiotic (alteration in membrane permeability), alteration of **the** target (mutations **at the** ribosomal level) and the most important, inactivation **of the** antibiotic **by** aminoglycoside modifying enzymes.

5.2 Pharmacokinetic particulars
Neomycin is poorly absorbed from the gastrointestinal tract. It is mostly excreted in the feces after oral administration.

5.3 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.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Wheat bran
Paraffin light liquid

Silicic acid precipitate and dry (E551a)

6.2 Incompatibilities
None known.

6.3 Shelf life
Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after incorporation into meal or pelleted feed: 3 months

6.4. Special precautions for storage
This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging
Bag consisting of four sheets of paper, the innermost of which is kraft paper that is in contact with the product. The borders are sealed by being sewn together.

Pack size: bag of 25 kg.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
Laboratorios Maymó, S.A.
Via Augusta, 302
08017, Barcelona (Spain).

8. MARKETING AUTHORISATION NUMBER
XXXXX

9. DATE OF FIRST AUTHORISATION AND RENEWAL OF THE AUTHORISATION, IF APPROPIATE
Date of first authorisation: DD/MM/YYYY

10 DATE OF REVISION OF THE SPC
MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE