SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEOMAY 500 000 IU/g powder for use in drinking water/milk replacer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:
Active substance:
Neomycin (as neomycin sulphate)500 000 IU
Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for use in drinking water/milk replacer.
White or almost white powder.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (calves), pigs (weaned and fattening pigs), chickens (including laying hens), ducks, turkeys (including turkey hens), geese, quail and partridges.

4.2 Indications for use, specifying the target species

For treatment of gastrointestinal infections caused by *E. coli* susceptible to neomycin.

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active substance, to aminoglycosides or to any of the excipients.
Do not use in cases of intestinal obstruction.

4.4 Special warnings for each target species

Medicated drinking water intake can be affected by the severity of the disease. In case of insufficient intake of water/milk replacer, calves and pigs should be treated parenterally.

4.5 Special precautions for use

Special precautions for use in animals
Powder for oral solution that is to be dissolved in water and cannot be used as it is.
Special care should be taken when considering administration of the product to the newborn calf due to the known higher gastrointestinal absorption of neomycin in neonates. This higher absorption could lead to an increased risk of oto- and nephrotoxicity. The use of the product in neonates should be based on the benefit/risk determination from the attending veterinarian.

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

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to neomycin and may decrease the effectiveness of treatment with aminoglycosides due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
People with known hypersensitivity to aminoglycosides should avoid contact with the veterinary medicinal product.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in animals have not produced any evidence of teratogenic effects of neomycin.
The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay in the target species.

Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and others

General anaesthetics and muscle relaxing products increase the neuro-blocking effect of aminoglycosides. This may cause paralysis and apnoea.
Special care should be taken when using concurrently with diuretics and potentially oto- or nephrotoxic substances.

4.9 Amounts to be administered and administration route

In drinking water/milk replacer use.
25 000 IU of neomycin per kg bodyweight per day for 3 to 4 consecutive days, corresponding to 5 g of veterinary medicinal product per 100 kg bodyweight per day for 3 to 4 days.
The following formula may be used to calculate the required amount of veterinary medicinal product in g per litre drinking water/milk replacer:

$$\text{g of product per} = \frac{\text{g of product/kg b.w. /day} \times \text{mean body weight (kg) of animals to be treated}}{}$$

l drinking water/milk replacer Mean daily water/milk replacer consumption (l) per animal

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of neomycin has to be adjusted accordingly.
The maximum solubility of the powder is 255 000 IU of neomycin/ml (510 g of product/L) of water.
For the administration of the product commercially available dosing pumps can be used.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Nephrotoxic and/or ototoxic effects may occur in case of accidental overdose.

4.11 Withdrawal periods

Cattle (Calves).
Meat and offal: 14 days.
Pigs (weaned and fattening pigs) - meat and offal – 3 days
Chickens (including laying hens), ducks, turkeys, turkey hen, goose, quail and partridge.
Meat and offal: 14 days.
Eggs: zero 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. Aminoglycosides have a broad antibacterial spectrum with good activity against Gram negative species, especially *Escherichia coli* and less activity against Gram positive species. This class of antimicrobials has no effect against anaerobic bacteria.
Neomycin binds to the 30S subunit of the bacterial ribosome which disturbs the reading of the constituent code of the RNA messenger, and finally the synthesis bacterial protein. At high concentrations, it has been shown that aminoglycosides damage the cell wall, conferring bactericidal and bacteriostatic properties.
The resistance mechanisms are complex and differ between aminoglycoside molecules. Four mechanisms of resistance have been identified: changes of the ribosome, reduction of permeability, inactivation by enzymes and substitution of the molecular target. The common mechanism of resistance is the production of aminoglycoside modifying enzymes. These resistance mechanisms can be located in mobile genetics elements increasing the likelihood of spread of aminoglycoside resistance as well as co and cross-resistance. The level of resistance of pathogenic *E. coli* towards neomycin in calves in Europe ranges between 20 and 50 %.

5.2 Pharmacokinetic particulars

Neomycin is poorly absorbed from the gastrointestinal tract. Absorption from the gastrointestinal tract can be significant in neonates. 90% of neomycin is excreted in the faeces after oral administration.

Environmental properties.

The active ingredient neomycin sulfate is persistent in the environment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate.

6.2 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution in drinking water: 24 hours.
Shelf life after dilution in milk replacer: use immediately.

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

Bags composed of a triple complex film formed by a polyester film, an aluminum film and a sheet of low density polyethylene joined by a polyurethane base adhesive, closed by thermal system.

Pack size: bag of 100 g and 1 kg.
Not all pack sizes may be marketed

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

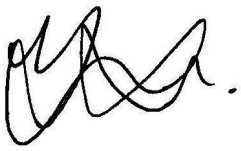
Vm 42204/4001

9. DATE OF FIRST AUTHORISATION

09 January 2017

10. DATE OF REVISION OF THE TEXT

October 2020



Approved: 09 October 2020