

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

### 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.

White or almost white powder.

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

Cattle (calves), pigs (weaned and fattening pigs), chickens (including layer 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 sensitive to neomycin.

#### 4.3 Contraindications

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

Medicated drinking water intake can be affected by the severity of the disease. In case of insufficient intake of water, cattle 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 to administer 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 crossresistance.

### 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.

### Other precautions

None.

## 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 evaluated in the target species.

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

## 4.8 Interaction with other medicinal products and other forms of interaction

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 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:

g of product/kg b.w. /day

x

mean body weight (kg)

g of product per =

of animals to be treated

l drinking water/milk

Mean daily water/milk 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 Period(s)

Cattle.  
Meat and offal: 14 days.

Pigs.  
Weaned and fattening pigs: 3 days

Chickens, layer hen, ducks, turkeys, turkey hen, goose, quail and partridge.  
Meat and offal: 14 days.  
Eggs: zero days.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL 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 properties

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 Incompatibilities

None known.

### 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 formed by a complex of metalized polyester film and low density polyethylene film, bound together with polyurethane adhesive, closed by a thermal system.

Pack size: bag of 100 g and 1 kg.

## **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

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(S)**

VPA 10436/003/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 23<sup>rd</sup> December 2016

## **10 DATE OF REVISION OF THE TEXT**