[Version 9.1, 11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEOMAY [FR]
NEOMAY 500 000 IU/g [ES]
NEOMAY powder for use in drinking water/milk replacer [DK, PT]
NEOMAY 500 000 IU/g powder for use in drinking water/milk replacer [IT, EL, HU, IE, PL, NI, CZ, RO, SK, SI, HR]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:
Neomycin (as neomycin sulphate) ..... 500 000 IU

Excipient:

Qualitative composition of excipients and other constituents
Lactose monohydrate

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves), pig (weaned and fattening pigs), chicken (including laying hens), duck, turkey (including turkey hens), goose, quail and partridge.

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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 veterinary

medicinal product in neonates should be based on the benefit/risk determination from the attending veterinarian.

Use of the veterinary medicinal 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 veterinary medicinal product is used.

Use of the veterinary medicinal 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:

People with known hypersensitivity to aminoglycosides should avoid contact with the veterinary medicinal product.
Wash hands after use.
In case of accidental spillage onto skin or exposure by inhalation or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay in the target species.

Pregnancy, lactation and laying birds:
Use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in animals have not produced any evidence of teratogenic effects of neomycin.

3.8 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.

3.9 Administration routes and dosage

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.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{g of veterinary medicinal product /kg bodyweight/day} \times \text{average bodyweight (kg) of animals to be treated}}{\text{Average daily water/milk replacer intake (L/ animal)}} = \text{g of veterinary medicinal product per L of drinking water/milk replacer}$$

To ensure a correct dosage body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

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

The maximum solubility of the powder is 255 000 IU of neomycin/ml (510 g of veterinary medicinal product/L) of water.
For the administration of the veterinary medicinal product commercially available dosing pumps can be used.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
ATCvet code: QA07AA01

4.2 Pharmacodynamics

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 %.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

5.2 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 according to directions: 24 hours.
Shelf life after dilution in milk replacer according to directions: use immediately.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 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

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Maymó, S.A.U.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

BAG of 100 g and 1 Kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEOMAY [FR]
NEOMAY 500 000 IU/g [ES]
NEOMAY powder for use in drinking water/milk replacer [DK, PT]
NEOMAY 500 000 IU/g powder for use in drinking water/milk replacer [IT, EL, HU, IE, PL, NI, CZ, RO, SK, SI, HR]

2. COMPOSITION

Each g contains:
Neomycin (as neomycin sulphate) 500 000 IU
Excipient, q.s. 1 g

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

3. PACKAGE SIZE

100 g
1 kg

4. TARGET SPECIES

Cattle (calves), pig (weaned and fattening pigs), chicken (including laying hens), duck, turkey (including turkey hens), goose, quail and partridge.

5. INDICATIONS FOR USE

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

6. CONTRAINDICATIONS

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

7. SPECIAL WARNINGS

Special warnings

<u>Special warnings:</u>
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.

Special precautions for safe use in the target species:
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 veterinary medicinal 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 veterinary medicinal product in neonates should be based on the benefit/risk determination from the attending veterinarian.

Use of the veterinary medicinal 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 veterinary medicinal product is used.

Use of the veterinary medicinal 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:
People with known hypersensitivity to aminoglycosides should avoid contact with the veterinary medicinal product.

Wash hands after use.

In case of accidental spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Pregnancy, lactation and laying birds:
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.

Laboratory studies in animals have not produced any evidence of teratogenic effects of neomycin.

Interactions 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.

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

Special restrictions for use and special conditions for use:
Not applicable.

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

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

8. ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder, the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
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.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\text{g of veterinary medicinal product per litre of drinking water / milk replacer} = \frac{\text{g of product / kg bodyweight day x average bodyweight(kg) of animals to be treated}}{\text{average daily water / milk replacer intake (l/animal))}}$$

To ensure a correct dosage body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of neomycin may need to be adjusted accordingly.
The maximum solubility of the powder is 255 000 IU of neomycin/ml (510 g of veterinary medicinal product/L) of water.
For the administration of the veterinary medicinal product commercially available dosing pumps can be used.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

11. WITHDRAWAL PERIODS

Withdrawal periods
Cattle (Calves)
Meat and offal: 14 days.
Pigs (weaned and fattening pigs)
Meat and offal: 3 days
Chickens, laying hen, ducks, turkeys, turkey hen, goose, quail and partridge.
Meat and offal: 14 days.

Eggs: zero days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

This veterinary medicinal product does not require any special storage conditions

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems.

Ask your veterinary surgeon how to dispose of medicine no longer required. These measures should help to protect the environment.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
To be supplied only on veterinary prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes

Bag of 100 g
Bag of 1 kg

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

<{MM/YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Laboratorios Maymó, S.A.U.
Vía Augusta, 302
08017 Barcelona (Spain)
Tel: +34 932 370 220

Local representatives <and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

18. OTHER INFORMATION

Other information

Environmental properties
The active ingredient neomycin sulfate is persistent in the environment.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy} Once opened use by:…….
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution in drinking water according to directions: 24 hours.
Shelf life after dilution in milk replacer according to directions: use immediately.

21. BATCH NUMBER

Lot {number}