

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {100 g and 1 Kg PACKAGE SIZES:}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

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.

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 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 or its local representative using the contact details on this label, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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:

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

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 (including laying hens), 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. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicine no longer required.

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

Vm 42204/4001

Pack sizes

Bag of 100 g

Bag of 1 kg

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Laboratorios Maymo, S.A.U.
Vía Augusta 302
08017 Barcelona (Spain)
Tel: +34 932 370 220

Local representatives and contact details to report suspected adverse reactions:

Vetsonic (UK) Ltd
Tel: 01653 695333
07887420538
ellen.stephenson@vetsonic.com

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

POM-V

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 {month/year}

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}

Gavin Hall
Approved: 24 July 2025