LABELLING AND PACKAGE LEAFLET

LABEL-LEAFLET FOR 100 g and 1 Kg PACKAGE SIZES:

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

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder:
Laboratorios e Industrias IVEN, S.A.
Luís I, 56
28031 MADRID (Spain)

Manufacturer responsible for batch release:
Laboratorios Maymó, S.A.
Vía Augusta, 302
08017 Barcelona (Spain)

2. Name of the veterinary medicinal product

NEOIVEN 500 000 IU/g powder for use in drinking water/milk replacer
Neomycin (as neomycin sulphate)

3. Statement of the active substance and other ingredients

Each g contains:
Neomycin (as neomycin sulphate) 500 000 IU
Excipient, q.s. ..... 1 g
White or almost white powder.

4. Pharmaceutical form

Powder for use in drinking water /milk replacer

5. Package size

Bag of 100 g and 1 kg

6. Indication (s)

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

7. Contraindications

Do not use in case of hypersensitivity to the active substance, to aminoglycosides or to the excipients or in the presence of intestinal obstruction

8. Adverse reactions

None known.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon .Alternatively you can report via your national reporting system {national system details}.

9. Target species

Cattle (calves), pigs (weaned and fattening pigs), chickens, layer hen, ducks, turkeys, turkey hen, goose, quail and partridge.

10. Dosage for each species, route(s) 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.

The following formula may be used to calculate the required amount of veterinary medicinal product in g per litre drinking water/milk replacer:

$$\text{g of product per l drinking water/milk replacer} = \frac{\text{g of product/kg b.w. /day} \times \text{mean body weight (kg) of animals to be treated}}{\text{Mean daily water/milk replacer consumption (l) per animal}}$$

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.

11. Advice on correct administration

12. 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.

13. Special storage precautions

This veterinary medicinal product does not require any special storage conditions
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

14. Special warnings

<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, animals should be treated parenterally.

<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 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.

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

<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 strong diuretics and potentially oto- or nephrotoxic substances.

<Overdose (symptoms, emergency procedures, antidotes)>:
Nephrotoxic and/or ototoxic effects may occur in case of an accidental overdose.

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

15. Special precautions for the disposal of unused product or waste materials, if any

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

16. Date on which the label was last approved

July 2020

<17. Other information>

Pack sizes:
Bag of 100 g
Bag of 1 kg

Not all pack sizes may be marketed

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}

Once opened use by: …….
Shelf life after first opening the container: 6 months.
Shelf life after dilution in drinking water: 24 hours.
Shelf life after dilution in milk replacer: use immediately.

21. Marketing Authorisation Number

Vm 48749/4000

22. Manufacturer's batch number

Lot {number}

Approved 04 May 2023