SUMMARY OF PRODUCT CHARACTERISTICS

The format of this leaflet was determined by the Ministry of Health and its contents was checked and approved by it.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neo-Vine Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Neomycin sulfate 100%

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Turkeys

4.2 Indications for use, specifying the target species

For the treatment of gastro-intestinal infections caused by micro-organisms sensitive to neomycin in turkeys.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance, to aminoglycosides or in the presence 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, animals 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.

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 and lay.

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

Do not administer to breeding flocks

4.8 Interaction with other medicinal products and others 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.

4.9 Amounts to be administered and administration route

In drinking water use.

From the age of 1 day to 1 week: 1 gram per 15 liters of drinking water for 3 to 6 consecutive days.

From the age of 2 weeks to 8 weeks: 1 gram per 10 liters of drinking water for 3 to 6 consecutive days.

From the age of 9 weeks onward: 1 gram per 5.5 liters of drinking water for 3 to 6 consecutive days.

Administer to the flock as the sole source of drinking water.

A fresh solution should be prepared every 4 hours.

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 an accidental overdose.

4.11 Withdrawal periods

Turkeys: 4 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

None

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

The expiry date of the product is indicated on the packaging materials
Shelf life after first opening the immediate packaging: to the end of shelf life when stored under 25ºC
Shelf life after dilution in drinking water: 4 hours at 25ºC .

6.4 Special precautions for storage

Store under 25ºC

6.5 Nature and composition of immediate packaging

White HDPE bottle with a white LDPE lid containing 50 or 500 grams of powder.
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

Abic Veterinary Products Ltd. POB 489, Beit Shemesh Industrial Zone, Israel.

8. MARKETING AUTHORISATION NUMBER

079-46-91288

9. DATE OF REVISION OF THE TEXT

January 2021