

ANNEX 3

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 g sachet / 1 kg bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Novosol 500 000 IU/g Powder for Use in Drinking Water/Milk for Cattle, Chickens, Pigs, Ducks, Turkeys, Geese, Quail and Partridges

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains

Active substance:

Neomycin (as Neomycin sulfate)500 000 IU

3. PACKAGE SIZE

100 g

1 kg

4. TARGET SPECIES

Cattle (pre-ruminant), pigs (weaned and fattening pigs), chickens (including laying hens), ducks, turkeys (including turkey hens), geese, quail and partridges.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water/milk replacer use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle (calves):

Meat and offal: 14 days.

Pigs (weaned piglets and pigs for fattening):

Meat and offal: 3 days.

Chickens, ducks, turkeys, geese, quail and partridge:

Meat and offal: 14 days.

Eggs: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the immediate packaging: 6 months

Shelf life after dissolution in drinking water according to directions: 24 hours

Shelf life after incorporation into milk replacer according to directions: 2 hours

Once opened used by...

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBER

Vm 30282/3030

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Novosol 500 000 IU/g Powder for Use in Drinking Water/Milk for Cattle, Chickens, Pigs, Ducks, Turkeys, Geese, Quail and Partridges

2. Composition

Each g contains

Active substance:

Neomycin (as Neomycin sulfate)500 000 IU

White to light yellow fine powder

3. Target species

Cattle (pre-ruminant), pigs (weaned and fattening pigs), chickens (including laying hens), ducks, turkeys (including turkey hens), geese, quail and partridges.

4. Indications for use

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

5. 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.

6. Special warnings

Special warnings

Cross-resistance has been shown between neomycin and different aminoglycoside antibiotics in *Escherichia coli*. Use of the veterinary medicinal product/neomycin should be carefully considered when susceptibility testing has shown resistance to aminoglycoside antibiotics because its effectiveness may be reduced.

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 identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should

be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Co-selection for other classes of antimicrobials is common (see section 4.2 for further details).

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Aminoglycosides may cause hypersensitivity (allergy) following ingestion, inhalation, or skin contact.

People with known hypersensitivity to neomycin or other aminoglycosides should avoid contact with the veterinary medicinal product.

Aminoglycosides may be harmful following ingestion, eye or skin contact and inhalation.

Handle this veterinary medicinal product with great care to avoid dermal exposure, including hand and mouth contact. Avoid inhalation of dust.

Wear personal protective equipment consisting of appropriate protective clothes, gloves, glasses and disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143 when handling the veterinary medicinal product.

Wash hands after use.

In the event of eye or skin contact, rinse the affected area with large amounts of clean water.

In case of accidental ingestion, immediately rinse the mouth with water and seek medical advice immediately and show the package leaflet or the label to the physician.

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 and lay:

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

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

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 diuretics and potentially oto- or nephrotoxic substances.

Overdose

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

Major incompatibilities:

This veterinary medicinal product may be administered using drinking water containing hydrogen peroxide at a maximum concentration of 35 ppm.

This veterinary medicinal product must not be administered using hard water containing chlorine.

This veterinary medicinal product may be administered using soft water containing chlorine at a maximum concentration of 1 ppm.

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

7. Adverse events

Cattle (pre-ruminant), pigs (weaned and fattening pigs), chickens (including laying hens), ducks, turkeys (including turkey hens), geese, quail and partridges:
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 in this package leaflet, 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. 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 (i.e. 5 g of veterinary medicinal product per 100 kg bodyweight per day), for 3 to 4 days.

To ensure a correct dosage body weight should be determined as accurately as possible.

The intake of medicated water or medicated milk replacer 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 use of suitably calibrated measuring equipment is recommended.

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:

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

9. Advice on correct administration

The maximum solubility of the veterinary medicinal product is 255 000 IU of neomycin/mL (510 g of veterinary medicinal product/L) of water.

The veterinary medicinal product should be incorporated in the milk replacer having a temperature between 21 and 30°C. To achieve the dissolution of the veterinary medicinal product in milk replacer, a vigorous stirring for 10 minutes should be applied.

For the administration of the veterinary medicinal product commercially available dosing pumps can be used.

10. Withdrawal periods

Cattle (calves):

Meat and offal: 14 days.

Pigs (weaned and fattening pigs):

Meat and offal: 3 days.

Chickens, ducks, turkeys, geese, quail and partridge:

Meat and offal: 14 days.

Eggs: zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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.

Shelf life after first opening the container: 6 months

Shelf life after dissolution in drinking water according to directions: 24 hours

Shelf life after incorporation into milk replacer according to directions: 2 hours.

12. 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 or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 30282/3030

100 g sachet
1 kg bag

Not all pack sizes may be marketed.

15. 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.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium
+32 3 288 18 49

Manufacturer responsible for batch release:

HUVEPHARMA SA
34 rue Jean Monnet
ZI d'Etriché
Segré
49500 Segré-en-Anjou Bleu
France

Local representatives and contact details to report suspected adverse reactions:

17. Other information

Environmental properties

The active ingredient neomycin sulfate is persistent in the environment.

Approved 10 December 2025

Gavin Hall