

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE { Bottle of 125 ml,  
250 ml, 500 ml or 1 L }**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Paroform 140 mg/ml solution for use in drinking water/ milk

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

140 mg paromomycin base equivalent to 200 mg paromomycin sulfate or 140.000 IU of paromomycin activity

**3. PACKAGE SIZE**

125 ml,  
250 ml,  
500 ml  
1 L

**4. TARGET SPECIES**

Cattle (pre-ruminant), pigs.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

In drinking water/milk use.

**7. WITHDRAWAL PERIODS**

Withdrawal period:

Cattle (pre-ruminant)

Meat and offal: 20 days

Pigs

Meat and offal: 3 days

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 3 months. Once opened use by....

Medicated drinking water, milk or milk replacer should be refreshed or replaced every 6 hours (in milk/milk replacer) or every 24 hours (in water).

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C.

**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 NUMBERS**

Vm 30282/4033

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Paroform 140 mg/ml solution for use in drinking water/milk for cattle (pre-ruminant) and pigs.

**2. Composition**

Each ml contains:

**Active substance:**

140 mg paromomycin base equivalent to 200 mg paromomycin sulfate or 140.000 IU of paromomycin activity

**Excipients:**

Methyl parahydroxybenzoate (E218)	1.0 mg
Propyl parahydroxybenzoate	0.1 mg
Sodium metabisulphite (E223)	4.0 mg
Purified water	

A clear yellow to amber solution.

**3. Target species**

Cattle (pre-ruminant), pigs.

**4. Indications for use**

Treatment of gastro-intestinal infections caused by *Escherichia coli*

**5. Contraindications**

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

Do not use in cases with impaired function of the kidneys or liver.

Do not use in ruminating animals.

Do not use in turkeys due to the risk of selection for antimicrobial resistance in intestinal bacteria.

## **6. Special warnings**

### Special warnings:

Cross-resistance has been shown between paromomycin and some antimicrobials in the aminoglycosides class in *Enterobacterales*. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to aminoglycosides because its effectiveness may be reduced. Paromomycin selects for resistance and cross-resistances at high frequency against a variety of other aminoglycosides among intestinal bacteria.

### Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s) isolated from the animal. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogen at farm level or at local/regional level. Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of water/milk animals should be treated parenterally using a suitable injectable veterinary medicinal product following the advice of the veterinarian.

The use of the veterinary medicinal product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking. Since the veterinary medicinal product is potentially ototoxic and nephrotoxic, it is recommended to assess kidney function.

Special care should be taken when considering administration of the veterinary medicinal product to newborn animals due to the known higher gastrointestinal absorption of paromomycin 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 a benefit/risk assessment by the responsible veterinarian.

Prolonged or repeated use of the veterinary medicinal product should be avoided by improving management practices and through cleansing and disinfection.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to paromomycin and may decrease the effectiveness of treatment with aminoglycosides due to the potential for crossresistance.

Aminoglycosides are considered as critical in human medicine. Consequently, they should not be used as a first line treatment in veterinary medicine.

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

This veterinary medicinal product contains paromomycin, which can cause allergic reactions in some people.

People with known hypersensitivity to paromomycin should avoid contact with the veterinary medicinal product.

Avoid contact with the skin and eyes.

Personal protective equipment consisting of protective clothing and impervious gloves should be worn when handling the veterinary medicinal product.

In case of accidental contact with the skin or eyes, rinse with plenty of water.

If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the package leaflet or the label to the the physician. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Do not eat, drink and smoke when handling the veterinary medicinal product.

Do not ingest. In case of accidental ingestion or spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

### Pregnancy:

Laboratory studies in rat and rabbit have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The use is not recommended during the pregnancy.

### Interaction with other medicinal products and other forms of interaction:

General anaesthetics and muscle relaxants increase the neuro-blocking effect of aminoglycosides, which can lead to acute paralysis and apnoea. Do not use concurrently with loop diuretics and potentially oto- or nephrotoxic substances.

### Overdose:

Paromomycin when administered orally is hardly resorbed. Harmful effects due to accidental overdosing is highly unlikely.

### Major incompatibilities:

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.

Rare (1 to 10 animals / 10,000 animals treated):	Loose stool (diarrhea)
Undetermined frequency (cannot be estimated from available data)	Nephropathy <sup>1</sup> Internal ear disorder <sup>1</sup>

<sup>1</sup> Aminoglycoside antibiotics such as paromomycin can cause nephro- and ototoxicity.

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 using the contact details at the end of this leaflet, or via your national reporting system:

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

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## 8. Dosage for each species, routes and method of administration

In drinking water/milk use

Cattle (pre-ruminant):

For administration in milk/milk replacer.

25-50 mg paromomycin sulfate per kg BW/day (equivalent to 0.125 – 0.25 ml of veterinary medicinal product/kg BW/day).

Duration of treatment: 3-5 days.

Pigs:

For administration in drinking water.

25-40 mg paromomycin sulfate per kg BW/day (equivalent to 0.125 – 0.2 ml of veterinary medicinal product/kg BW/day).

Duration of treatment: 3-5 days.

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

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::

$$\frac{\text{ml veterinary medicinal product}}{\text{product/ kg body weight / day}} \times \frac{\text{mean body weight (kg) of animals to be treated}}{\text{Mean daily water/milk/milk replacer consumption (l/animal)}} = \dots \text{ ml veterinary medicinal product per litre drinking water/milk/milk replacer}$$

The intake of medicated water/milk /milk replacer depends on several factors including the clinical condition of the animals and the local conditions such as ambient temperature and humidity. In order to obtain the correct dosage, drinking water/milk/milk replacer uptake has to be monitored and the concentration of paromomycin may need to be adjusted accordingly.

## 9. Advice on correct administration

Medicated drinking water/milk/milk replacer and any stock solutions should be freshly prepared by carefully mixing the veterinary medicinal product in the requisite quantity

of fresh potable water /milk/milk replacer every 6 hours (in milk/milk replacer) or every 24 hours (in water).

## **10. Withdrawal periods**

Cattle (pre-ruminant)

Meat and offal: 20 days

Pigs

Meat and offal: 3 days

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 25°C.

After reconstitution, 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 bottle after "Exp". The expiry date refers to the last day of that month.

Shelf life after first opening of the immediate packaging: 3 months

Shelf life after reconstitution in drinking water: 24 hours

Shelf life after reconstitution in milk/milk replacer: 6 hours

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

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 30282/4033

Pack size: bottles of 125 ml, 250 ml, 500 ml and 1 L.

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](http://www.gov.uk).

### **16. Contact details**

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

Huvepharma NV  
Uitbreidingstraat 80  
2600 Antwerpen  
Belgium  
+32 3 288 18 49  
[pharmacovigilance@huvepharma.com](mailto:pharmacovigilance@huvepharma.com)

Manufacturer responsible for batch release

Biovet JSC  
39 Petar Rakov Str  
4550 Peshtera  
Bulgaria

### **17. Other information**

POM-V

Environmental properties:

The active ingredient paromomycin sulfate is very persistent in the environment.

*Gavin Hall*  
Approved: 24 April 2025