

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paroform crypto 140 000 IU/ml oral solution for sheep and goats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

140 000 IU of paromomycin activity (as paromomycin sulfate)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl parahydroxybenzoate (E218)	1.0 mg
Propyl parahydroxybenzoate	0.1 mg
Sodium metabisulfite (E223)	4.0 mg

A clear yellow to amber solution.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (pre-ruminant) and goats (pre-ruminant).

3.2 Indications for use for each target species

Reduction of the severity and the duration of diarrhoea associated with *Cryptosporidium parvum* in individual animals confirmed to have cryptosporidial oocysts in their faeces.

Paromomycin reduces faecal oocyst shedding.

3.3 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.

3.4 Special warnings

Lambs and goat kids should only receive the treatment upon confirmation of cryptosporidial oocysts in their faeces and as soon as possible after the onset of diarrhoea (see section 3.5).

In field studies investigating the effect of the veterinary medicinal product on diarrhoea associated with cryptosporidiosis, the median duration of clinically relevant diarrhoea was 3 days for treated lambs compared to 6 days for untreated lambs and 4 days in treated kid goats compared to 7 days for the untreated goats, during the 7-day treatment period.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

Aminoglycosides are considered as critically important in human medicine. 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 cross-resistance.

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 or to any other aminoglycosides should avoid contact with the veterinary medicinal product.

Avoid contact with the skin and eyes.

In the event 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 physician. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Personal protective equipment consisting of protective clothing and impervious gloves should be worn when handling the veterinary medicinal product. Do not eat, drink and smoke when handling the veterinary medicinal product.

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

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sheep and goats:

Undetermined frequency (cannot be estimated from available data)	Nephropathy (nephrotoxicity) ¹ Internal ear disorder (ototoxicity) ¹
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¹can be caused by aminoglycoside antibiotics such as paromomycin

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

General anaesthetics and muscle relaxing products increases the neuro-blocking effect of aminoglycosides. This may cause paralysis and apnoea.

Do not use concurrently with strong diuretics and potentially oto- or nephrotoxic substances.

3.9 Administration routes and dosage

For oral use.

Dose rate: 35 000 IU of paromomycin /kg BW /day for 7 consecutive days, i.e. 0.25 ml of veterinary medicinal product / 1 kg BW/day for 7 consecutive days.

The consecutive treatment should be done at the same time each day.

To ensure a correct dosage, bodyweight should be determined as accurately as possible and the use of either a syringe or any appropriate device for oral administration is necessary.

Only a single course of treatment should be administered to an individual animal.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

At 5 times the dose and 3 times the duration, no adverse effects have been observed in lambs.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 24 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QA07AA06.

4.2 Pharmacodynamics

Paromomycin has antiprotozoal activity, although its mechanism of action is unclear. In *in vitro* studies using HCT-8 and Caco-2 cell lines inhibitory activity against *C. parvum* was observed.

Resistance of cryptosporidia to paromomycin has not been described to date. Nevertheless, the use of aminoglycosides is associated with the occurrence of bacterial resistance. Paromomycin may select for cross-resistance to other aminoglycosides.

4.3 Pharmacokinetics

IV injection in lambs at a dose rate of 7 000 IU / kg showed that paromomycin is rapidly eliminated ($T_{1/2} = 4.58$ hours) and that the clearance (2.49 ml/min/kg) was relatively low showing probably limited liver metabolism.

The bioavailability of paromomycin when administered as a single oral dose of 50 mg paromomycin sulphate/kg bodyweight to lambs was 13%. With regard to the absorbed fraction, the mean peak plasma concentration (C_{max}) was 2.68 mg/l, the mean time to attain the peak plasma concentration (T_{max}) was 4 hours and the mean terminal half-life ($t_{1/2, el}$) was 27.4 hours. The main part of the dose is eliminated unchanged in the faeces.

Environmental properties

The active ingredient paromomycin is very persistent in the environment.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 3 months.

5.3. Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

White high-density polyethylene bottles with tamper-evident polypropylene screw closures.

Pack sizes are

125 ml

250 ml

500 ml

1 L

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection system applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

7. MARKETING AUTHORISATION NUMBER(S)

VPA10782/033/001

8. DATE OF FIRST AUTHORISATION

05/07/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

06/12/2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).