

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parofor crypto 140 000 IU/ml oral solution for pre-ruminant cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

140 000 IU of paromomycin activity

Excipients:

Methyl parahydroxybenzoate (E218)	1.0 mg
Propyl parahydroxybenzoate	0.1 mg
Sodium metabisulfite (E223)	4.0 mg

For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Oral solution.

A clear yellow to amber solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (pre-ruminant).

4.2 Indications for use, specifying the target species

Reduction in the occurrence of diarrhoea due to diagnosed *Cryptosporidium parvum*.

Calves should only receive the veterinary medicinal product upon confirmation of cryptosporidial oocysts in their faeces and before the onset of diarrhoea.

Paromomycin reduces faecal oocyst shedding.

4.3 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.

4.4 Special warnings for each target species

In field studies investigating the effect of the veterinary medicinal product on diarrhoea associated with cryptosporidiosis, 23% to 32% of calves in treated groups presented with diarrhoea, in comparison to 53% to 73% of calves in untreated groups, during the 7-day treatment period.

4.5 Special precautions for use

Special precautions for use in animals

The use of the veterinary medicinal product should be combined with good management practices e.g. good hygiene, proper ventilation and no overstocking. Repeated use of the veterinary medicinal product on farms should be avoided by improving management practices and through cleaning 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.

The safety of the veterinary medicinal product has not been investigated in animals less than 3 days of age.

Special precautions to be take 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 any other aminoglycoside 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 clean 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.

Other precautions:

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 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.

4.9 Amount(s) to be administered and administration route

For oral use.

Dose rate: 35 000 IU of paromomycin/kg BW/day for 7 consecutive days, i.e. 2.5 ml of veterinary medicinal product / 10 kg BW/day for 7 consecutive days.

To ensure a correct dosage, the use of either a syringe or an appropriate device for oral administration is necessary and the veterinary medicinal product should be administered directly in the mouth of the animal.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Do not administer for more than 7 days since clinical signs associated with gastrointestinal lesions were observed after prolonged treatment duration. In 2 to 5 week old calves, overdoses in excess of 35 000 IU paromomycin/kg bodyweight may induce gastrointestinal lesions (ulceration, pustules, chronic hyperplastic inflammation) mostly in the rumen and reticulum. Bruxism and poor appetite have been reported. Repeated overdose may be associated with death.

4.11 Withdrawal periods

Due to accumulation of paromomycin in the liver and kidneys, any repeated course of treatment during the withdrawal period must be avoided.

Meat and offal: 62 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: intestinal anti-infectives; antibiotics.

ATC Vet Code: QA07AA06

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

The bioavailability of paromomycin when administered as a single oral dose of 35 000 IU paromomycin/kg bodyweight to 2 - 6 week old calves was 2.75%. With regard to the absorbed fraction, the mean peak plasma concentration (C_{max}) was 1.48 mg/l, the mean time to attain the peak plasma concentration (T_{max}) was 4.5 hours and the mean terminal half-life ($t_{1/2, el}$) was 11.2 hours. The main part of the dose is eliminated unchanged in the faeces while the absorbed fraction is excreted almost exclusively in urine as unchanged paromomycin. Paromomycin displays age-related pharmacokinetics, with the greatest systemic exposure occurring in newborn animals.

5.3 Environmental properties

The active ingredient paromomycin is very persistent in soil.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate

Sodium metabisulfite (E223)

Water, purified

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

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

White high density polyethylene bottle with tamper-evident screw polypropylene closure.

Bottle sizes are:

125 ml

250 ml

500 ml

1 L.

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

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 30282/5012

9. DATE OF FIRST AUTHORISATION

19 July 2018

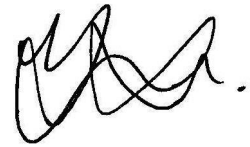
10. DATE OF REVISION OF THE TEXT

December 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 28 April 2024