Huvepharma NV
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Parofor crypto 140 mg/ml oral solution for non-ruminant calves

Species: Cattle

Therapeutic indication:Pharmaceuticals: Endoparasiticides: Antiprotozoals

Active ingredient: Paromomycin sulphate

Product: Parofor crypto 140 mg/ml oral solution for non-ruminant calves

Product index: Parofor Crypto (calves)

Cattle - meat:62 days

Incorporating:

Presentation

Oral solution.

A clear yellow to amber solution.

Each ml contains:

Active substance:

140 000 IU of paromomycin activity

Excipients:

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate

Sodium metabisulphite (E223)

Purified water

Uses

Target species

Cattle (pre-ruminant calves).

Indications for use

Reduction in the occurrence of diarrhoea due to diagnosed Cryptosporidium parvum. Calves should only receive the product upon confirmation of cryptosporidial oocysts in their faeces and before the onset of diarrhoea. Paromomycin reduces faecal oocyst shedding.

Dosage and administration

For oral use.

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

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

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

Contra-indications, warnings, etc

Do not use in animals with known hypersensitivity to paromomycin, other aminoglycosides or any of the excipients.

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

Do not use in ruminating animals.

Special warnings for each target species

In field studies investigating the effect of the 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.

Special precautions for use in animals

The use of the product should be combined with good management practices e.g. good hygiene, proper ventilation and no overstocking. Repeated use of the 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 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 product has not been investigated in animals less than 3 days of age.

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

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

People with known hypersensitivity (allergy) to paromomycin or any other aminoglycosides should avoid contact with the 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 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 physician this warning. 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 product.

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

Wash hands after use.

Adverse reactions (frequency and seriousness)

Aminoglycoside antibiotics such as paromomycin can cause oto- and nephrotoxicity.

Use during pregnancy, lactation or lay

Not applicable.

Overdose (symptoms, emergency procedures, antidotes)

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 50 mg paromomycin sulphate/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.

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.

Pharmaceutical precautions

List of excipients

Methyl parahydroxybenzoate (E218) 1.0mg

Propyl parahydroxybenzoate 0.1mg

Sodium metabisulfite (E223) 4.0mg

Purified water

Major Incompatibilities

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

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.

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

Pharmacological Immunological Properties

Pharmacotherapeutic group: intestinal anti-infectives; antibiotics.

ATCvet code: QP 51 AA 06.

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..

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 (Cmax) was 1.48 mg/l, the mean time to attain the peak plasma concentration (Tmax) was 4.5 hours and the mean terminal half-life (t1/2, 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.

Environmental properties

The active ingredient, paromomycin sulphate, is persistent in soil.

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 products should be disposed of in accordance with local requirements.

Legal category

Legal category:POM-V

Packaging quantities

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.

Special precautions for storage: Do not store above 25°C.

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.

Marketing Authorisation Holder (if different from distributor)

Huvepharma NV

Uitbreidingstraat 80

2600 Antwerpen

Belgium

Further information

Nil.

Marketing Authorisation Number

Vm 30282/4036

Significant changes

GTIN

GTIN description:125 ml Plastic bottle

GTIN:5414916626400

GTIN description:250 ml Plastic bottle

GTIN:5414916626417

GTIN description:500 ml Plastic bottle

GTIN:5414916626424

GTIN description:1 litre Plastic bottle

GTIN:5414916626431