PACKAGE INSERT FOR

PAROFOR CRYPTO 140 mg/ml ORAL SOLUTION

VETERINARY MEDICINE

SCHEDULING STATUS

S4

PROPRIETY NAMES AND DOSAGE FORMS

PAROFOR CRYPTO 140 mg/ml ORAL SOLUTION

COMPOSITION

Each ml contains:

Paromomycin Sulfate equivalent to Paromomycin 140 mg

Excipients:

Methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate, sodium metabisulfite

PHARMACOLOGICAL CLASSIFICATION

C.17.1.3 Aminoglycoside Antibiotic

PHARMACOLOGICAL ACTION

Pharmacodynamic Properties

Paromomycin has antiprotozoal activity, although its mechanism of action is unclear. The optimal *in-vitro* concentration of paromomycin exerting inhibitory activity against *C. parvum* was 400 µg /ml. Paromomycin reduces faecal oocyst shedding.

Pharmacokinetic Properties

The bioavailability of paromomycin when administered as a single oral dose of 50 mg paromomycin sulphate/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 apparent elimination half-life ($t_{1/2}$, el) was 11.2 hours. The clearance was low (1.65 ml/kg/min) and the volume of distribution (0.84 l/kg) suggests that paromomycin is not restricted to the extracellular fluid space. The absorbed fraction is excreted almost exclusively in urine as unchanged paromomycin.
Paromomycin is poorly absorbed from the gastrointestinal tract and most of the dose is eliminated unchanged in faeces

Paromomycin displays age-related pharmacokinetics, with the greatest systemic exposure occurring in new-born animals.

Environmental properties

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

INDICATIONS

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

CONTRAINDICATIONS

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.

WARNINGS AND SPECIAL PRECAUTIONS

Special warnings for each target species

Animals should receive enough colostrum according to good breeding practice.

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

Special precautions for use in animals

Since the product is potentially ototoxic and nephrotoxic, it is recommended to assess kidney function.

Special care should be taken when considering administration of the product to new-born 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 product in neonates should be based on a benefit/risk assessment by the responsible veterinarian.

Withdrawal Period(s)

Meat and offal: 62 days

Special precautions to be taken by the person administering **PAROFOR 140 ORAL SOLUTION** ***to animals***

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 and seek medical attention of irritation persists.

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.

INTERACTIONS

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.

PREGNANCY AND LACTATION

The safety of the product has not been established in pregnant or lactating cattle. This product is only indicated for use in pre-ruminant calves. Therefore, the use of the product is not recommended in these animals.

DOSAGE AND DIRECTIONS FOR USE

50 mg of paromomycin sulphate /kg BW /day for 7 consecutive days, i.e. 2.5 ml of product / 10 kg BW/day for 7 consecutive days.

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

On farms with a history of *cryptosporidiosis* confirmed by positive oocyst count, treat all newborn calves on that farm before the age of 48 hours.

To ensure correct dosing, the use of either a syringe or an appropriate device for oral administration is necessary.

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

SIDE-EFFECTS

On rare occasions, soft faeces have been observed.

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

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF IT'S TREATMENT

Do not administer for more than 7 days. 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.

IDENTIFICATION

A clear yellow to amber solution.

PRESENTATION

PAROFOR CRYPTO 140 mg/ml ORAL SOLUTION is packed into White HDPE bottles of 125 ml, 250 ml, 500 ml and 1 L with tamper-evident screw PP closure.

Not all pack sizes may be marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Keep well closed.

KEEP OUT OF REACH AND SIGHT OF CHILDREN

REGISTRATION NUMBER

19/10

NAME AND BUSINESS ADDRESS OF HOLDER OF THE CERTIFICATE OF REGISTRATION

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