ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parofor crypto 140 000 IU/ml oral solution.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

140 000 IU of paromomycin activity

3. PACKAGE SIZE

125 ml
250 ml
500 ml
1000 ml

4. TARGET SPECIES

Cattle (pre-ruminant)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

Withdrawal period:
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.

8. EXPIRY DATE

Exp: {mm/yyy}
Shelf life after first opening the immediate packaging: 3 months. Once opened use by….

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 NUMBER

Vm 30282/3014

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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

A clear yellow to amber solution.

3. Target species

Cattle (pre-ruminant).

4. Indications for use

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.

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.

6. Special warnings

Special warnings:
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.

Special precautions for safe use in the target species:
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 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 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.

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.

Overdose:
Do not administer for more than 7 days. 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.

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:

Undetermined frequency (cannot be estimated from available data)	Nephropathy (nephrotoxicity) [1] Internal ear disorder (ototoxicity)[1]

[1]can be caused by aminoglycoside antibiotics such as paromomycin

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

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.

9. Advice on correct administration

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

10. 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

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.
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 the immediate packaging: 3 months

12. Special precautions for disposal

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 applicable national collection system. These measures should help to protect the environment.
Ask your veterinary surgeon 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

White high density polyethylene bottle with tamper-evident screw polypropylene closure.
Pack size: bottles of
125 ml
250 ml
500 ml
1 L.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

December 2023

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

16. Contact details

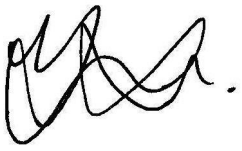
Marketing authorisation holder and contact details to report suspected adverse reactions
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

Local representatives and contact details to report suspected adverse reactions

17. Other information

Environmental properties:
The active ingredient paromomycin is very persistent in soil.



Approved: 28 April 2024