# 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 for pre-ruminant cattle.
Paromomycin

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

140 000 IU of paromomycin activity

## 3. PHARMACEUTICAL FORM

Oral solution

## 4. PACKAGE SIZE

125 ml
250 ml
500 ml
1000 ml

## 5. TARGET SPECIES

Cattle (pre-ruminant calves)

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

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.

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

Shelf life after first opening: 3 months. Once opened use by….

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4036

## 17. MANUFACTURER'S BATCH NUMBER

Lot:

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET FOR:

Parofor crypto140 000 IU/ml oral solution for pre-ruminant cattle

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

**Marketing authorisation holder:**
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

**Manufacturer responsible for batch release:**
Biovet JSC
39 Petar Rakov Str
4550 Pesthera
Bulgaria

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

**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.

A clear yellow to amber solution.

## 4. INDICATION(S)

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.

## 5. 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.

## 6. ADVERSE REACTIONS

Aminoglycoside antibiotics such as paromomycin can cause oto- and nephrotoxicity.
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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

## 7. TARGET SPECIES

Cattle (pre-ruminant calves).

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 product / 10 kg BW/day for 7 consecutive days.

## 9. ADVICE ON CORRECT ADMINISTRATION

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

## 10. 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

## 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 of the immediate packaging: 3 months

## 12. SPECIAL WARNING(S)

**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**

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.

Use during pregnancy, lactation or lay

Not applicable.

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 (symptoms, emergency procedures, antidotes), if necessary

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.

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

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

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

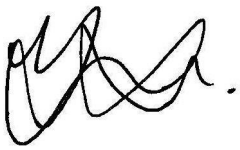
Dispose of any waste veterinary medicinal product in accordance with local requirements. Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

## 15. OTHER INFORMATION

Pack size: bottles of
125 ml
250 ml
500 ml
1 L.

Not all pack sizes may be marketed.



Approved: 17 February 2023