# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**White HDPE bottle with tamper-evident screw PP closure of 125 ml, 250 ml, 500 ml and 1 L**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parofor crypto140 000 IU/ml oral solution for sheep and goats.
Paromomycin.

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

**Active substance:**

140 000 IU of paromomycin activity (as paromomycin sulfate)

## 3. PHARMACEUTICAL FORM

Oral solution.

## 4. PACKAGE SIZE

1 L
500 ml
250 ml
125 ml

## 5. TARGET SPECIES

Sheep (pre-ruminant lambs) and goats (pre-ruminant kids).

## 6. INDICATION(S)

*** For those Member States where space permits ***

Reduction of the severity and the duration of diarrhoea associated with *Cryptosporidium parvum* in individual animals confirmed to have cryptosporidial oocysts in their faeces.
Paromomycin reduces faecal oocyst shedding.

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

For oral use.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Withdrawal period
Meat and offal: 24 days

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

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP
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 30282/3015

## 17. MANUFACTURER'S BATCH NUMBER

Batch number:

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## Parofor crypto 140 000 IU/ml oral solution for sheep and goats

## 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 Peshtera
Bulgaria

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parofor Crypto 140 000 IU/ml oral solution for sheep and goats.
Paromomycin

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

**Each ml contains:**

**Active substance:**

140 000 IU of paromomycin activity (as paromomycin sulfate)

**Excipients:**

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

A clear yellow to amber solution.

## 4. INDICATION(S)

Reduction of the severity and the duration of diarrhoea associated with *Cryptosporidium parvum* in individual animals confirmed to have cryptosporidial oocysts in their faeces.
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

Sheep (pre-ruminant lambs) and goats (pre-ruminant kids).

## 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. 0.25 ml of product / 1 kg BW/day for 7 consecutive days.

## 9. ADVICE ON CORRECT ADMINISTRATION

The consecutive treatment should be done at the same time each day.
To ensure correct dosing, the bodyweight should be determined as accurately as possible and the use of either a syringe or any appropriate device for oral administration is necessary.
Only a single course of treatment should be administered to an individual animal.

## 10. WITHDRAWAL PERIOD

Meat and offal: 24 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

Lambs and goat kids should only receive the treatment upon confirmation of cryptosporidial oocysts in their faeces and as soon as possible after the onset of diarrhoea.

In field studies investigating the effect of the product on diarrhoea associated with cryptosporidiosis, the median duration of clinically relevant diarrhoea was 3 days for treated lambs compared to 6 days for untreated lambs and 4 days in treated kid goats compared to 7 days for the untreated goats, during the 7-day treatment period.

### Special precautions for use in animals

Since the product is potentially ototoxic and nephrotoxic, it is recommended to assess kidney function, especially when considering administration of the product to newborn 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.

The use of the product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking and through cleansing and disinfection.
Aminoglycosides are considered as critically important in human medicine. Use of the product deviating from the instructions given in the package leaflet 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.

### 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 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 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.
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 product.
Do not ingest. In case of accidental ingestion, seek medical advice immediately and show the label to the physician.
Wash hands after use.

### Pregnancy

Not applicable.

### Interaction with other medicinal products and other forms of interaction

General anaesthetics and muscle relaxing products increases 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

At 5 times the dose and 3 times the duration, no adverse effects have been observed in lambs.

### 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 the environment.

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

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

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

## 15. OTHER INFORMATION

Pack sizes:
1 L
500 ml
250 ml
125 ml.
Not all pack sizes may be marketed.

Approved 26 October 2023