PACKAGE LEAFLET FOR VETERINARY MEDICINAL PRODUCT

This medicine is dispensed with a veterinarian's prescription only
For veterinary use only

1. NAME OF THE MEDICINE, ITS FORM AND STRENGTH:

Cryptofor 140,000 IU/ml Veterinary

Oral solution for sheep and goats

2. COMPOSITION:

Each ml contains:

Active substance:
140,000 IU of paromomycin activity.

Excipients:

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

For the full list of excipients, see section 13 "Other Information".

3. WHAT IS THE MEDICINE INTENDED FOR?

Reduction of the severity and the duration of diarrhoea associated with *Cryptosporidium parvum* in individual animals confirmed to have cryptosporidial oocyst in their faeces. Paromomycin reduces faecal oocyst shedding.
Therapeutic group: other antiprotozoal agents

4. 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.

5. 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}.

You can report side effects to the Ministry of Health by clicking on the link “Report side effects resulting from medicinal treatment” found on the homepage of the Ministry of Health website (www.health.gov.il), which will direct you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

6. TARGET SPECIES

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

7. DOSAGE FOR EACH SPECIES, ROUTE 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.

8. HOW TO USE THE MEDICINAL PRODUCT

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.

9. WITHDRAWAL PERIOD

Meat and offal: 24 days

10. WARNINGS

Special warnings regarding the use of the medicine in the 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 for maintaining the safety of the person handling the medicinal product

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 medicines 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.

11. STORAGE INSTRUCTIONS

Avoid poisoning! This medicine, as well as all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, in order to prevent poisoning.

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. INSTRUCTIONS REGARDING DISPOSAL OF THE MEDICINAL PRODUCT/ REMAINDER OF THE MEDICINAL PRODUCT AFTER USE

Any remaining veterinary medicinal product or any waste produced during use of the medicinal product must be disposed of as toxic waste. Do not discard via wastewater.

13. OTHER INFORMATION

In addition to the active substance, this medicinal product also contains:
Purified water, Sodium metabisulfite, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate

What the medicine looks like and what the package contains
A white plastic bottle with a white screw cap and a tear strip, containing a clear yellow to amber solution.

Package size: Bottles of 125 ml, 250 ml, 500 ml and 1 liter.

Not all pack sizes may be marketed.

Name and address of the license holder:

M. P. Vet Ltd., POB 7004, Petah Tikva 49170

Name and address of the manufacturer:
Biovet JSC
39 Petar Rakov Str
4550 Pesthera

Bulgaria

This leaflet was approved in September 2023

Registration number of the medicinal product in the Ministry of Health National Drug Registry:
174-04-36500-99