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:

Parofor 140,000 IU/ml
Veterinary

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

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

3. WHAT IS THE MEDICINE INTENDED FOR?

Reduction in the occurrence of diarrhea due to *Cryptosporidium parvum* diagnosed in pre-ruminant cattle.
Calves should only receive the medicinal product upon confirmation of cryptosporidial oocysts in their feces and before the onset of diarrhea.
Paromomycin reduces fecal oocyst shedding.
Therapeutic group: Antibiotic for intestinal infections

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.
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

Cattle (pre-ruminant calves).

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., 2.5 ml of the medicinal product / 10 kg BW/day for 7 consecutive days.

8. HOW TO USE THE MEDICINAL PRODUCT

To ensure correct dosing, the use of 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.

9. 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

10. WARNINGS

Special warnings regarding the use of the medicine in the target species
In field studies investigating the effect of the medicinal product on diarrhea associated with cryptosporidiosis, 23% to 32% of calves in treated groups presented with diarrhea, in comparison to 53% to 73% of calves in untreated groups, during the 7-day treatment period.

Special precautions for use in animals
The use of the medicinal 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 have special importance in human medicine. Use of the medicinal product deviating from the instructions given in this medicinal product's 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.
The safety of the medicinal product has not been investigated in animals less than 3 days of age.

Special precautions for maintaining the safety of the person handling the medicinal product
This medicinal 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 medicinal product.
Avoid contact with the skin and eyes.

Personal protective equipment consisting of protective clothing and impervious gloves should be worn when handling this 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 or 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 calving
Not applicable.

Interaction with other medicines and other forms of interaction
General anesthetics and muscle relaxing medicinal products increase the neuro-blocking effect of aminoglycosides. This may cause paralysis and apnea.
Do not use concurrently with strong diuretics or with 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.

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.

11. STORAGE INSTRUCTIONS

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

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.

Do not store above 25°C.

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 January 2022

Registration number of the medicinal product in the Ministry of Health National Drug Registry: 169-06-35917-00