GABBROVET® POWDER

Product information

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gabbrovet 70, 70 mg/g. Powder for administration in drinking water/milk.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g of powder contains:

Active substance:

Paromomycin (as sulfate)..... 70 mg
(equivalent of paromomycin activity)..... 70 000 IU
(equivalent to approximately 100 mg of paromomycin sulfate)

Excipients..... qs 1g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for administration in drinking water/milk.

4. CLINICAL PARTICULARS

4.1 | Target species

Cattle (pre-ruminant cattle), pigs.

4.2 | Indications for use, specifying the target species

Treatment of gastro-intestinal infections caused by *Escherichia coli* susceptible to paromomycin.

4.3 | 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.
Do not use in turkeys due to the risk of selection for antimicrobial resistance in intestinal bacteria.

4.4 | Special warnings for each target species

None.

4.5 | Special precautions for use

i Special precautions for use in animals

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of water/milk animals should be treated parenterally using a suitable injectable product following the advice of the veterinarian.

The use of the product should be combined with good management practices e.g. good hygiene, proper ventilation, no overstocking.

Since the product is potentially ototoxic and nephrotoxic, it is recommended to assess kidney function. Special care should be taken 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 benefit-risk assessment by the responsible veterinarian.

Prolonged or repeated use of the product should be avoided by improving management practices and through cleansing and disinfection. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Official, national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the given instructions 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.

Aminoglycosides are considered as critical in human medicine. Consequently, they should not be used as a first intention treatment in veterinary medicine.

ii Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity (allergy) to paromomycin or any other aminoglycosides should avoid contact with the product.

Personal protective equipment consisting of protective clothing and impervious gloves should be worn when handling the product.

Do not eat, drink and smoke when handling the product.

In case of accidental ingestion, seek medical advice immediately and show the label to the physician.

When handling this product, it is imperative to avoid inhaling dust by wearing a disposable half mask respirator complying with European standard EN 149 or a non-disposable respirator in accordance with European standard EN 140 with a filter in accordance with EN 143.

Use in a well-ventilated area. Avoid inhalation of powder when preparing with water or water or milk replacer. Avoid contact with the skin and eyes. In the event of accidental contact with the skin or eyes, rinse thoroughly with water and contact a physician if the irritation persists.

4.6 | Adverse reactions (frequency and seriousness)

In rare occasions soft faeces has been observed.

Aminoglycoside antibiotics such as paromomycin can cause oto- and nephrotoxicity.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 | Use during pregnancy, lactation or lay

Laboratory studies in the rat and rabbit have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The use is not recommended during pregnancy.

4.8 | 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.

4.9 | Amounts to be administered and administration route

Oral use.

Pre-ruminant cattle: administration in milk.

Pigs: administration in drinking water.

Duration of treatment: 3-5 days.

Pre-ruminant cattle: 25-50 mg paromomycin sulphate per kg BW/day, equivalent to 17500 - 35000 IU paromomycin per kg BW/day (approximately equivalent to 2.5-5 g veterinary drug per 10 kg BW/day).

Pigs: 25-40 mg paromomycin sulphate per kg BW/day, equivalent to 17500 - 28000 IU paromomycin per kg BW/day (approximately equivalent to 2.5-4 g veterinary drug per 10 kg body weight per day).

For the administration through the drinking water the exact daily amount of veterinary medicinal product should be based on the number of the animals to be treated, and the recommended dose calculated according to the following formula:

$$\frac{\text{ml product/ kg BW/day} \times \text{Mean bodyweight (kg) of animals to be treated}}{\text{Mean daily water consumption (litre) per animal}} = \text{ml product per litre drinking water per day per animal.}$$

To ensure a correct dosage bodyweight should be determined as accurately as possible. The uptake of medicated water depends on several factors including clinical conditions of the animals and the local conditions such as ambient temperature and humidity. In order to obtain the correct dosage, uptake of drinking water has to be monitored and the concentration of paromomycin has to be adjusted accordingly.

A properly calibrated scale should be used to ensure that the required daily amount of product is administered accurately.

4.10 | Overdose (symptoms, emergency procedures, antidotes), if necessary

Paromomycin when administered orally is hardly absorbed systemically. Harmful effects due to accidental overdosing are highly unlikely.

4.11 | Withdrawal periods

Cattle:

Meat and offal: 20 days

Pigs:

Meat and offal: 3 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: intestinal antiinfectives; antibiotics; paromomycin.
ATCvet code: QA07AA06.

5.1 | Pharmacodynamic properties

Paromomycin belongs to the group of aminoglycoside antibiotics. Paromomycin changes the reading of messenger-RNA, which disrupts protein synthesis. The bactericidal activity of paromomycin is mainly attributed to its irreversible binding to ribosomes. Paromomycin has broad spectrum activity against numerous Gram-positive and Gram-negative bacteria, including *E. coli.*

Paromomycin acts in a concentration-dependant manner. Five mechanisms of resistance have been identified: changes of the ribosomes due to mutations, reduction of permeability of bacterial cell wall or active efflux, enzymatic modification of ribosomes and inactivation of aminoglycosides by enzymes. The first three resistance mechanisms arise from mutations of certain genes on bacterial chromosome. The fourth and fifth resistance mechanism only occurs following uptake of mobile genetic elements coding for resistance. Paromomycin selects for resistance and cross-resistances at high frequency against a variety of other aminoglycosides among intestinal bacteria.

5.2 | Pharmacokinetic particulars

Following oral administration of paromomycin, hardly any absorption takes place and the molecule is eliminated unchanged via the faeces.

5.3 | Environmental properties

The active ingredient paromomycin sulfate is persistent in the environment.

6. PHARMACEUTICAL PARTICULARS

6.1 | List of excipients

Colloidal silicon dioxide
Dextrose monohydrate

6.2 | Major incompatibilities

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

6.3 | Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months

The shelf life of the veterinary medicinal product after dissolution in water and milk is 24 hours.

6.4 | Special precautions for storage

Store at a temperature not exceeding 25°C.
Store in the original packaging.

6.5 | Nature and composition of immediate packaging

Metalic pot of 1 kg.

6.6 | Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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