SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Bolus 12 g, Continuous Release Intraruminal Device

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Each 12 g intraruminal device contains:

Qualitative composition	Quantitative composition in g
Fenbendazole	12

Excipients

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Continuous Release Intraruminal Device.
A cylindrical intraruminal device, consisting of 10 grey/black flat-faced intraruminal devices in a magnesium alloy tube, enclosed by plastic rings.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

The intraruminal device treats and prophylactically controls gastrointestinal nematode infections in cattle caused by *Ostertagia* spp., *Trichostrongylus* spp., *Haemonchus* spp., *Cooperia* spp and *Oesophagostomum* spp. The intraruminal device aids in the control of parasitic bronchitis caused by *Dictyocaulus viviparus.*

For use in ruminating cattle in their first grazing season weighing between 100kg and 300kg on the day of administration. When administered at turnout, the intraruminal device controls parasitic gastroenteritis throughout the grazing season by reducing the build up of infective larvae on the pasture. Reduced pasture contamination in the autumn lowers the risk of inhibited *Ostertagia* larvae accumulating in sufficient numbers to cause winter

ostertagiasis. When administered later in the season, the intraruminal device is effective in the treatment of established parasitic infections and continues to have a prophylactic effect up to 140 days after administration. This period may be reduced if cattle are moved to heavily infected pasture.

4.3 Contra-indications

Do not use in pre-ruminating cattle, cattle weighing less than 100kg or cattle less than 3 months of age.
Do not administer to cattle over 300kg.

4.4 Special warning for each target species

If an intraruminal device treated animal is sold during the season, the purchaser must be informed of the date on which the intraruminal device was administered.

The intraruminal device can interfere with the detection of foreign bodies (hardware disease) by an electronic metal detector.
Immunity to nematodes depends on adequate exposure to infection. Although not normally the case, circumstances could occur in which anthelmintic control measures might increase the vulnerability of cattle to re-infection. Animals may be at risk towards the end of their first grazing season, particularly if the season is long, or in the following year if they are moved onto heavily contaminated pasture. In such circumstances, further control measures may be necessary.

Where specific preventative control of lungworm is required it is advised that cattle are given an appropriate lungworm vaccine. As the product allows a small percentage of lungworm to reach the lungs when cattle are exposed, it will not interfere with the development of immunity.

Under conditions of heavy larval challenge, clinical signs of lungworm may become evident. Therefore if clinical signs of lungworm occur in treated cattle they should be dosed immediately with an appropriate anthelmintic. Without additional control measures, such as vaccination, lungworm infestations can sometimes occur during the life of the intraruminal device.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk dosing programmes should be discussed with veterinary surgeon.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Under dosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of

the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to benzimidazoles has been reported in *Teladorsagia, Haemonchus, Cooperia* and *Trichostrongylus* species in small ruminants. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

(i) Special precautions for use in animals

Administer the intraruminal device gently and with great care.
If lungworm vaccination is practised in cattle before turnout, the intraruminal device should not be administered until 14 days after the second dose of vaccine has been given.
Ensure all animals weigh more that 100kg/bw. Do not administer concurrently with other medicinal intraruminal devices.

In very rare cases, mild to severe oesophageal lesions might occur if the product is not used as recommended.

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

Wash hands after use. Direct contact with the skin should be kept to a minimum.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy or lactation

The product has been used successfully and without undesirable effects in pregnant cows but is not intended for use in this class of animal.

4.8 Interaction with other medicinal products and other forms of interaction

None known. However, the product has not been evaluated for compatibility with other medicinal intraruminal devices yet and therefore use with other medicinal intraruminal devices is not recommended.

4.9 Amounts to be administered and administration route

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

One intraruminal device to be administered orally to each animal before being turned out to grass. Alternatively, animals which have already been turned out can be administered an intraruminal device later in the grazing season.

All animals within a group grazing the same pasture must be treated with a Panacur Bolus to ensure maximum benefits from the system.

All newcomers to the group must also be administered a Panacur Bolus before being turned out to grass.

Administration is achieved using the Panacur Bolus Applicator which helps to administer the intraruminal device directly into the top of the oesophagus.

Insert an intraruminal device into the applicator. Restrain the animal and extend the head forward, keeping the neck straight. Insert the applicator into the front of the mouth and firmly but gently push it over the back of the tongue. Keeping the neck straight, tilt the head upwards and the animal will begin to swallow the end of the applicator - indicated by easier passage of the applicator down the throat.
The intraruminal device can then be ejected into the oesophagus by squeezing the release trigger on the applicator. Do not use force when administering the intraruminal device. Observe the animal for a short time to ensure the intraruminal device has been swallowed.

As the metal of the intraruminal device can be detected, the correct position of the intraruminal device can be checked by a suitable metal detector.

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

Benzimidazoles have a high margin of safety. No specific overdose symptoms are known. No specific actions required.

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 200 days from administration of the intraruminal device.
Not for use in cattle producing milk for human consumption or to dairy heifers within 200 days of parturition.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fenbendazole is an anthelmintic belonging to the benzimidazole-carbamates group. It acts by interfering in the energy metabolism of the nematode.

The anthelmintic affects both adult and immature stages of gastro-intestinal and respiratory nematodes. This anthelmintic efficacy is based on inhibition of the polymerisation of tubulin to microtubuli.

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5.2 Pharmacokinetic particulars

The Panacur bolus remains in the reticulum or rumen and disintegrates over time with an increased loss of rings. The release rate of the intraruminal device ranges from 0.23-1.04 mg fenbendazole/kg/day. Fenbendazole is only partly absorbed from the gastrointestinal tract.
Fenbendazole is metabolised mainly by enzymes of the cytochrome P -450 system in the liver. The major oxidative metabolite is fenbendazole sulfoxide which is further metabolised to fenbendazole sulfone. Other metabolites are p-hydroxyfenbendazole and fenbendazole amine, the major urinary metabolite.
Fenbendazole and its metabolites are distributed throughout the body and high concentrations can be found in the liver.
Fenbendazole and its metabolites are undetectable in the plasma at 127-131 days after administration.
The elimination of fenbendazole and its metabolites occurs primarily via the faeces and to a small extent in the urine and milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Graphite
Steel shot

6.2 Incompatibilities

None known

6.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Store in a dry place. Do not store above 25°C.

6.5 Nature and composition of immediate packaging

1 Intraruminal device contained in polyvinyl blisters sealed onto an aluminium foil lined board.
The secondary packaging is a cardboard box that contains 10 individually packed intraruminal devices per box.

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.
Do not contaminate ponds, waterways or ditches with the product.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4087

9. DATE OF FIRST AUTHORISATION

01 December 1995

10. DATE OF REVISION OF TEXT

December 2024

Approved 10 December 2024
Gavin Hall