SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Bolus 12 g, Continuous Release Intraruminal Device for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each intraruminal device contains:

Active substance:

Fenbendazole 12 g

Excipients:

Qualitative composition of excipients and other constituents
Tablets:
Granulated sugar (sucrose)
Graphite
Steel shot
Tubes:
Magnesium
Aluminium
Copper
Plastic rings:
PVC hyvin compound
Masterbatch BN064: Iron oxide red pigment (Bayferrox 1120Z)
PVC resin

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each 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 100 kg and 300 kg 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.

3.3 Contraindications

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

3.4 Special warnings

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 veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Administer the intraruminal device gently and with great care.
In very rare cases, mild to severe oesophageal lesions might occur if the product is not used as recommended.
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 than 100 kg body weight. Do not administer concurrently with other medicinal intraruminal devices.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Direct contact with the skin should be kept to a minimum. Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Oral use.
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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

All newcomers to the group must also be administered the veterinary medicinal product 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 200 days.
Not authorised for use in cattle producing milk for human consumption or to dairy heifers within 200 days of parturition.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13

4.2 Pharmacodynamics

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 gastrointestinal and respiratory nematodes. This anthelmintic efficacy is based on inhibition of the polymerisation of tubulin to microtubuli.

4.3 Pharmacokinetics

The veterinary medicinal product 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.

Environmental properties
Fenbendazole is toxic to fish and other aquatic organisms.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

One 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.

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

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4087

8. DATE OF FIRST AUTHORISATION

01 December 1995

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

January 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 22 February 2026