Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur SR Bolus.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bolus contains:

Active Substance

Fenbendazole 12 g

For a full list of excipients see 6.1

3 PHARMACEUTICAL FORM

Slow release intra-ruminal device.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

The bolus treats and prophylactically controls gastro-intestinal nematode infections in cattle caused by *Ostertagia spp, Trichostrongylus spp, Haemonchus spp, Cooperia spp* and *Oesophagostomum spp.* The bolus controls parasitic bronchitis caused by *Dictyocaulus viviparus*.

For use in ruminating cattle weighing between 100kg and 300kg on the day of administration. When administered at turnout, the bolus 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 bolus 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 Contraindications

Do not use in cattle weighing more than 300 kg.
Do not use in preruminating cattle or cattle less than 3 months of age or less than 100kg of bodyweight.
Do not use in animals known to be hypersensitive to the active ingredient.
Do not administer concurrently with other medicinal bolus products.

4.4 Special warnings for each target species

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

The bolus 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 the following year if they are moved onto heavily contaminated pasture. In such instances, further control measures may be necessary.

4.5 Special precautions for use

Special precautions for use in animals

If lungworm vaccination is practised in cattle before turnout, the bolus should not be administered until 14 days after the second dose of vaccine has been given.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Fatalities may occur if the product is administered to animals less than 100 kg bodyweight.

4.7 Use during pregnancy, lactation or lay

The Panacur SR Bolus 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 bolus products and therefore use with other medicinal boluses is contra-indicated.

4.9 Amounts to be administered and administration route

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

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

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

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

Insert a bolus 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 bolus can then be ejected into the oesophagus by squeezing the release trigger on the applicator. Gently withdraw the applicator. Do not use force when administering the bolus. Observe the animal for a short time to ensure the bolus has been swallowed.
As the metal component of the bolus can be detected the correct position of the bolus can be checked by using a suitable metal detector.

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

Overdosing is highly unlikely, but no special precautions are required if overdose does occur.

4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 199 days from administration of the bolus.

Do not administer to cattle producing milk for human consumption or to dairy heifers within 199 days prior to parturition.

5 PHARMACOLOGICAL or IMMUNOLOGICAL 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.

5.2 Pharmacokinetic properties

The half-life of FBZ in serum after oral application of the recommended dose in cattle is 10-18 hours. FBZ and its metabolites are distributed throughout the body and high concentration can be found in the liver.

Fenbendazole is metabolised to its sulfoxide, then to sulfone and amines.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Graphite
Steel shot

6.2 Incompatibilities

None known.

6.3 Shelf-life

3 years.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and composition of immediate packaging

Polyvinyl chloride blisters sealed onto aluminium foil lined board. Each bolus is packed individually with 10 boluses in one outer carton.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Do not dispose of product or used package in ponds, waterways or ditches.

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.,
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/116/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21st November 2000 / 20 November 2005