PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/10 units}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Bolus 12 g Continuous Release Intraruminal Device

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 12 g Fenbendazole per intraruminal device.

3. PHARMACEUTICAL FORM

Each Bolus contains 12 g Fenbendazole.

4. PACKAGE SIZE

Contains 10 intraruminal devices.

5. TARGET SPECIES

6. INDICATION(S)

For the treatment and control of all major species of gastro-intestinal roundworms.

USES
The Panacur Bolus is designed to continuously release Fenbendazole in the recticulo-rumen of cattle for up to 140 days. Contains 12 g Fenbendazole per intraruminal device.
Roundworms: The intraruminal device treats and prophylactically controls gastrointestinal roundworm infections in cattle; Ostertagia app., Trichostrongylus spp., Oesophagostomum spp., Cooperia spp., Haemonchus spp.
For use in ruminating cattle weighing 100–300 kg on 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. This lowers the risk of inhibited Ostertagia larvae accumulating in sufficient numbers to cause winter ostertagiasis. When administered later in the season, the intraruminal device treats established parasitic infections and continues to control parasitic gastroenteritis for up to 140 days after administration. This period may be reduced if cattle are moved to heavily infected pasture.
The intraruminal device is also an aid in the control of parasitic bronchitis (Lungworm infection). Where specific preventative control of lungworm is required it is advised that cattle are treated with an appropriate lungworm vaccine. As Panacur Bolus allows a small percentage of lungworm to reach the lungs when cattle are exposed it will not interfere with the further development of immunity.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSAGE

One intraruminal device to be administered orally to each animal before turnout or later in the grazing season. See package leaflet for details.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS AND WARNINGS

For animal treatment only. Animals must not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption 200 days after administration of the intraruminal device. Do not administer to cattle producing milk for human consumption or to dairy heifers within 200 days of parturition.
See package leaflet for further warnings.
Keep intraruminal device in outer carton. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.
Do not contaminate ponds waterways or ditches with the product.

10. EXPIRY DATE

EXP end of: {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-VPS

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributed in Northern Ireland by:
INTERVET IRELAND Ltd,
Magna Drive, Magna Business Park
Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4447

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

Class of anthelmintic: 1-BZ

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Label/12 g}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Bolus 12 g Continuous Release

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains 12 g Fenbendazole.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

12 g.

4. ROUTE(S) OF ADMINISTRATION

Intraruminal device. For oral administration.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN: {number}

7. EXPIRY DATE

EXP end of: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

IMPORTANT: Remove Intraruminal device from this blister pack prior to administration.
Vm 01708/4447
Keep out of the sight and reach of children. Store in a dry place.
Do not store above 25°C.
Read the package leaflet before use.
To be supplied only on veterinary prescription.
Keep Intraruminal device in outer carton.
MSD Animal Health UK Ltd. Walton Manor, Walton. Milton Keynes, MK7 7AJ
Licensed distributor for Northern Ireland
INTERVET IRELAND Ltd. Magna Drive, Magna Business Park
Citywest Road, Dublin 24

PACKAGE LEAFLET FOR:

Panacur Bolus 12 g. Continuous Release Intraruminal Device

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ
UK

Manufacturer for the batch release:
Intervet Productions SA
Rue de Lyons
27460 Igoville
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur Bolus 12 g. Continuous Release Intraruminal Device.
Fenbendazole.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Active substance: Fenbendazole 12 g per 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. INDICATION(S)

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.

5. CONTRAINDICATIONS

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.

6. ADVERSE REACTIONS

None known. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Do not store above 25°C. Store in a dry place.
Keep intraruminal device in outer carton.

12. SPECIAL WARNING(S)

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.
Administer the intraruminal device gently and with great care. In very rare cases, mild to severe oesophageal lesions might occur of 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 that 100kg/bw. Do not administer concurrently with other medicinal intraruminal devices.
User warnings: Wash hands after use. Direct contact with the skin should be kept to a minimum.
Use during pregnancy: The product has been used successfully and without undesirable effects in pregnant cows but is not intended for use in this class of animal.
Interaction: None known. The product has not been evaluated for compatibility with other medicinal bolus products and therefore use with other medicinal boluses is contra-indicated.
Overdose: Benzimidazoles have a high margin of safety. No specific overdose symptoms are known. No specific actions required.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

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.
For animal treatment only.
Vm 01708/4447
POM-VPS
To be supplied only on veterinary prescription.
1-BZ

Approved: