1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Repidose Ready Pulse pulsatile-release intraruminal device for cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Oxfendazole 1250 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Indigo carmine aluminium lake - E132	20 mg
CELLULOSE MICROCRYSTALLINE	
Sodium starch glycolate (type A)	
Povidone K30	
Magnesium stearate	

A blue annular tablet with a slight bevel on the outside-edge.

Each pulsatile-release intraruminal device (bolus) contains:
7 tablets as above
1 PVC 7th tablet segment
6 PVC tablet segments
7 Silicone rubber sealing washers
1 Magnesium alloy core
1 Steel end-weight
1 PVC locking ring

3. CLINICAL INFORMATION

3.1 Target species

Cattle weighing between 100 kg and 400 kg.

3.2 Indications for use for each target species

For oral use in cattle weighing between 100 kg and 400 kg at the time the bolus is given.
In grazing cattle, the device will deliver seven doses of oxfendazole for the treatment of both adult and immature gastro-intestinal roundworms and lungworms and tapeworms at regular intervals of approximately three weeks during a period of about 18 weeks, the first dose being released within a few hours of administration. The device thus delivers a programmed therapeutic anthelmintic dosing regimen over a period of approximately 18 weeks from the time of dosing.

Oxfendazole is an established treatment for: Gastro-intestinal roundworms: *Ostertagia, Haemonchus, Trichostrongylus, Nematodirus, Cooperia, Bunostomum, Capillaria, Oesophagostomum, Chabertia, Trichuris;* Lungworms: *Dictyocaulus viviparus;* Tapeworms: *Moniezia* heads and segments.

At the recommended dose rate in cattle, oxfendazole is effective against inhibited larvae of *Cooperia* and up to 95 % effective against inhibited larvae of *Ostertagia.* Oxfendazole is also ovicidal against nematode eggs.

3.3 Contraindications

Do not use in non-ruminating calves or calves less than 12 weeks of age.
Do not use in animals weighing less than 100 kg or exceeding 400 kg.
Do not use the bolus concurrently with other bolus products.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Lungworm infestations which develop during the active life of the bolus and are present at the time of pulsing should be controlled by oxfendazole.
Under conditions of very heavy larval challenge, clinical signs of lungworm can become evident within 10 - 14 days of picking up an infection. Therefore, if clinical signs of lungworm occur in treated animals they should be dosed immediately with an appropriate anthelmintic. Lungworm infestations can sometimes develop during the active life of the bolus.

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.
- Underdosing, 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.

3.5 Special precautions for use

<u>Special precautions for safe use in the target species:</u>
Do not exceed the stated dose.
If lungworm vaccination is practised in calves before turnout, then the bolus should not be used until 10 – 14 days after the second dose of the vaccine has been given.
No other anthelmintic should be given to a treated animal whilst the bolus is still active except:
a) where clinical signs of a lungworm infestation become evident.
b) where dosing for liver fluke becomes necessary.

If a treated animal is sold, then the purchaser must be informed of the date on which the bolus was used.
As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing and also if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance might be involved.
The veterinary medicinal product with its programmed release of seven separate worming doses is designed specifically to allow a degree of nematode development for stimulation of immunity. 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 move onto heavily contaminated pasture. In such circumstances, further control measures may be necessary.
Worm control is best achieved when dosed animals are set stocked throughout the grazing season or moved to clean pasture in mid-summer. Worm control measures may be necessary after the active life of the bolus has come to an end. For example where animals are given the bolus early in the season or where winter housing is delayed and/or treated animals have been moved to potentially contaminated pasture.
Where an animal(s) is to be added to a group previously treated with the product, it is good management practice to minimise worm larval contamination of the pasture by incoming animal(s). This can be achieved by dosing with a bolus up to 24 hours before the move takes place.
Where cattle have received the bolus during their first grazing season at grass, it would be good practice, as with other anthelmintic dosing regimens, to maintain control measures during the following grazing season.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.

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

3.6 Adverse events

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 the national competent authority via the national reporting system. See package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Studies in cattle have not produced any evidence of foetotoxic or maternotoxic effects.
When used in lactating cattle, less than 1 % of the dose is excreted in the milk. Therefore, there is little risk to suckling animals when the product is used in lactating females.
Do not use in cattle producing milk for human consumption, or in cattle within 7 months of an expected calving date which precedes the production of milk for human consumption.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use the bolus concurrently with other bolus products.

3.9 Administration routes and dosage

Oral use.

Dose: One bolus should be administered to each animal as required.

Oral use by an oesophageal balling gun which delivers the bolus directly into the top of the gullet. When using the Bolus Applicator, insert the bolus into the balling gun with the metal end weight innermost. The applicator should be inserted from the front (not sides) of the mouth and over the back of the tongue, with no more than gentle, firm pressure. As the animal begins to swallow the end of the gun, the passage down the throat becomes easier. The applicator is now in position for firing. Depress the plunger to eject the bolus. Normal care should be taken not to cause injury by placing the gun too

far inside the throat of the animal. Ensure that each animal has swallowed the bolus by observing the animal for a short time after dosing.

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

There are no specific recommendations in the case of overdosage.

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: 7 months.

Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 7 months of expected parturition.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC02

4.2 Pharmacodynamics

Oxfendazole is an anthelmintic of the benzimidazole group. It is effective in the treatment and control of adult and immature gastro-intestinal roundworms and lungworms (including *Ostertagia, Haemonchus, Trichostrongylus, Nematodirus, Bunostomum, Cooperia, Capillaria, Oesophagostomum, Chabertia, Trichuris* and *Dictyocaulus*). It is also effective against roundworm eggs and tapeworms (*Moniezia*).
Oxfendazole acts on helminth parasites by inhibiting the fumarate reductase system and glycogen metabolism.

4.3 Pharmacokinetics

Absorption
Studies in cattle showed that the organic extractable portion of the radioactivity present in the plasma ranged from 99 % at 0.25 hours to 88 % at 8 to 12 hours after oral administration of 14-C oxfendazole. Approximately 77 % of the orally administered oxfendazole was absorbed.

Distribution
In oral 14-C oxfendazole studies in cattle, the liver was found to be the site of highest concentration and slowest depletion of drug-related residue. Total residues depleted with a half-life of 7 days. In cattle, liver protein-bound residue was shown to be only 13 % bioavailable as oxfendazole.

Biotransformation
Oxfendazole is metabolised into the thioether and the sulfone.

Elimination
In radiolabelled studies in cattle, about 21 % of the orally administered 14-C was recovered from the urine and 65 % from the faeces. Less than 1 % of oxfendazole is excreted in the milk, with a half-life being 18 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

5.3 Special precautions for storage

Store below 25 °C. Store in a dry place.

5.4 Nature and composition of immediate packaging

Intraruminal pulsatile-release device supplied as 24 boluses individually wrapped in Oriented Polyester/Aluminium foil/Oriented Polyamide/ Polyethylene and stored in a white polypropylene container with a polypropylene cap.

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

Medicines should not be disposed of via wastewater or household waste.

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 Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/254/001

8. DATE OF FIRST AUTHORISATION

01/10/1999

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

03/12/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).