Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Repidose Ready Pulse

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substance

Oxfendazole	1250 mg

Excipients

Indigo Carmine (F.D. & C Blue No. 2) Aluminium Lake (E132)	20 mg

For a full list of excipients, see section 6.1

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 PHARMACEUTICAL FORM

Pulsatile release, intraruminal device.
Each tablet is a blue annular tablet with a slight bevel on the outside-edge.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle weighing between 100 kg and 400 kg.

4.2 Indications for use, specifying the target species

For administration to 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 regime 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.

4.3 Contraindications

Do not administer to non-ruminating calves or calves less than 12 weeks of age.

Do not administer to animals weighing less than 100 kg or exceeding 400 kg.

Do not use the bolus concurrently with other bolus products.

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

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.

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.

4.5 Special precautions for use

Special precautions for use in animals
Do not exceed the stated dose.
If lungworm vaccination is practised in calves before turnout, then the bolus should not be administered 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 administered.
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.
Repidose 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 regimes, 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.

4.6 Adverse reactions (frequency and seriousness)

None when used as recommended.

4.7 Use during pregnancy, lactation or lay

Studies have shown that oxfendazole produces no adverse maternal or foetal effects when administered to pregnant cattle or sheep. When administered to lactating cattle and sheep, less than 1 % of the administered dose is excreted in the milk. Therefore, there is little risk to suckling animals when the product is administered to lactating females.
Do not administer to cattle producing milk for human consumption, nor to cattle within 7 months of an expected calving date which precedes the production of milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use the bolus concurrently with other bolus products.

4.9 Amounts to be administered and administration route

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

Administer orally by the use of 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.

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

There are no specific recommendations in the case of overdosage.

4.11 Withdrawal Period(s)

Meat & offal: 7 months after administration of the product.

Milk: Do not administer to cattle producing milk for human consumption, nor to cattle within 7 months of an expected calving date which precedes the production of milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics: OxfendazoleATCvet code: QP52AC02

5.1 Pharmacodynamic properties

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, Oesphagostomum, 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.

5.2 Pharmacokinetic properties

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 sheep and 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Sodium starch glycolate Type A
Povidone
Indigo Carmine (F.D. & C Blue No. 2) Aluminium Lake (E132)
Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

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

6.5 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.

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

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 or used containers.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

10996/254/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

July 2013