SUMMARY OF PRODUCT CHARACTERSITICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Autoworm First Grazer 8750 mg Pulsatile-Release Intraruminal Device

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituent	mg/tablet
Oxfendazole	1250.0
Excipients	
Indigo Carmine Lake (E132)	20.0

Each intraruminal device contains:
7 tablets each containing oxfendazole 1250 mg
1 PVC cap segment
7 PVC tablet segments
8 silicone rubber sealing washers
1 magnesium alloy core
1 steel end-weight

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pulsatile-release intraruminal device
A cylindrical device

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. Designed for dosing prior to turnout of cattle in their first grazing season.

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 approximately 21 weeks, the first dose being released around three weeks after administration. The device thus delivers a programmed therapeutic anthelmintic dosing regime over a period of approximately twenty-one weeks.

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

At the recommended dose rate in cattle, oxfendazole is effective against inhibited/arrested larvae of *Cooperia* and usually effective against inhibited/arrested larvae of *Ostertagia*.
It is also ovicidal against nematode eggs.

4.3 Contra-indications

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 exceed the stated dose.
Do not use the bolus concurrently with other bolus products, excepting Cosecure™, Rumbul™ Magnesium Bullets and Romensin™ RDD.

4.4 Special warning for each target species

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 bodyweight, 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 some parasite species in cattle. 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 seletion for resistance to anthelmintics.

4.5 Special Precautions for Use

i. Special precautions for use in animals

Take time to read the instructions carefully before starting the worming session.
Only gentle pressure should be used during bolus administration.
If lungworm vaccination is practised in calves before turnout, the bolus should not be administered until after the second dose of vaccine has been given, thus

ensuring that a period of at least three weeks elapses between lungworm vaccination and the release of the first dose of oxfendazole from the bolus.

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 likely development of anthelmintic resistance.
The 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 instances, further control measures may be necessary.
Worm control is best achieved when calves are dosed at turnout and set stocked throughout the grazing season, or moved to clean pasture in midsummer.

When an animal(s) is to be added to a group previously treated with an anthelmintic bolus then it is good management practice to minimise worm larval contamination of the pasture by the new animal(s). This can be achieved by dosing with an appropriate anthelmintic product at the time the animal is moved.

Where cattle have received the bolus during their first season at grass it would be good practice, as with other anthelmintic dosing regimes, to maintain control measures during the following season.

ii. Special precautions to be taken by the person administering the product to animals

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None when used as recommended.

4.7 Use During Pregnancy and Lactation

Studies have shown that oxfendazole produces no adverse maternal or foetal effects when administered at the recommended dose rate in cattle. When administered to lactating cattle, 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.

4.8 Interaction with Other Medicines and Other Forms of Interaction

Do not use the bolus concurrently with other bolus products, excepting Cosecure™, Rumbul™ Magnesium Bullets and Romensin™ RDD.

4.9 Amounts to be administered and route of Administration

Bodyweight should be determined as accurately as possible.

One bolus should be administered to each calf being turned out to pasture for the first grazing season. Alternatively, one bolus may be administered later in the season - ideally approximately three weeks before the first anthelmintic dose is normally required, or approximately one week before a move to pasture which has previously been contaminated by worm eggs.

Lungworm infestations which develop during the active life of the bolus and are present at the time of pulsing will 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.

Administration:

Administer orally using the Autoworm Bolus Applicator which delivers the bolus directly into the top of the gullet. When using the Autowonn 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 Periods

Do not slaughter animals for human consumption until at least eight months after administration of the product.

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

5. PHARMACOLOGICAL PROPERTIES

ATC Vet 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 Telodorsagia (*Ostertagia), Haemonchus, Trichostrongylus, Nematodirus*, *Cooperia, Capillaria, Oesphagostomum, Chabertia, Trichuris* and *Dictyocaulus*). It is also effective against roundworm eggs and tapeworms (*Moniezia*, heads and segments).
Oxfendazole acts by destroying the microtubular structure in the intestinal epithelium of helminths thus inhibiting the uptake of glycogen from the intestine of the parasite.

5.2 Pharmacokinetic properties

Absorption
The bolus is designed to deliver 7 successive 1250 mg doses of oxfendazole at approximately 3 weekly intervals starting about 3 weeks after administration.
Approximately 77 % of orally administered oxfendazole is absorbed by cattle.

Distribution
In oral ^{14}C oxfendazole studies in cattle, the liver was found to be the site of highest concentration and slowest depletion of the 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 % as 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 was excreted in the milk, with the half-life being 18 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Indigo Carmine Lake (E132)
Microcrystalline Cellulose
Sodium Starch Glycollate Type A
Povidone (K30)

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

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

6.5 Nature and Composition of immediate packaging

A cylindrical pulse release bolus device made up of a PVC cap segment, seven individual cells, corroding central alloy core and mild steel end weight of sufficient density to prevent regurgitation. Surrounding the central core each individual cell comprises a PVC segment, a blue circular, annular compressed tablet containing 1250 mg oxfendazole, and a silicone rubber sealing washer.
24 boluses individually wrapped in either:
a) PET/Aluminium/ LDPE
b) PET/ Aluminium/ OPA/ LDPE

And stored in white polypropylene container with a polypropylene tamper evident cap.

6.6 Special Precautions for the Disposal of Unused Product or Waste Material

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

Zoetis UK Limited
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KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4009

9. DATE OF FIRST AUTHORISATION

21 August 1998

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 21 August 2020