PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Autoworm Finisher 6250 mg Pulsatile-release Intraruminal Device

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each bolus contains 5 tablets each containing 1250 mg of oxfendazole

3. PHARMACEUTICAL FORM

Pulsatile-release Intraruminal Device

4. PACKAGE SIZE

24 boluses

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Designed for turnout dosing of cattle in their second grazing season.

Pulses for 15 weeks

A 5-dose programmed worming regime in a single bolus for treatment of roundworms (including lungworms and *Ostertagia*) and tapeworms. First dose released around three weeks after administration.

Knocks out worms and allows natural immunity to develop.

A pulse release bolus device for the treatment of gastro-intestinal roundworms and lungworms, both adult and immature, and also of tapeworms, at regular intervals of approximately three weeks during a period of about fifteen weeks. THE FIRST DOSE BEING RELEASED AROUND 3 WEEKS AFTER ADMINISTRATION. For cattle weighing between 100kg and 400kg at the time the bolus is given.

Oxfendazole is effective against inhibited/arrested larvae of *Cooperia* and usually effective against inhibited/arrested larvae of *Teladorsagia* (*Ostertagia*) in cattle. It also kills roundworm eggs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions for use

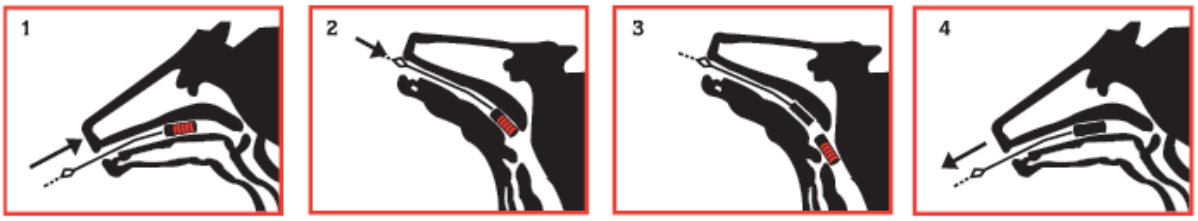
Take time to read the instructions carefully before starting the worming session.

Give a single bolus by mouth using the Autoworm Bolus Applicator which delivers the bolus into the top of the gullet. When using the Autoworm Bolus Applicator insert the bolus into the applicator 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 pressure**.

As the animal begins to swallow the end of the gun, the passage down the throat becomes easier. At this point, the applicator is in position for firing. Squeeze the trigger to eject the bolus.

Normal care should be taken not to cause any injury by placing the applicator 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.

Only gentle pressure should be used during bolus administration.



Dosage

One bolus should be administered to each animal being turned out to pasture for their second grazing season and weighing between 100 and 400kg. Bodyweight should be determined as accurately as possible.

Alternatively one bolus may be administered later in the grazing season - approximately three weeks before the first anthelmintic dose is normally required. 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 also sometimes develop after the active life of the bolus.

8. WITHDRAWAL PERIOD

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

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

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

9. SPECIAL WARNING(S), IF NECESSARY

For oral use only.

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

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

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

If lungworm vaccination is practised in calves before turnout, then 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.

Read package leaflet for anthelmintic resistance.

User Warnings:

Wash hands after use.**10. EXPIRY DATE**

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in a dry place. Protect from frost

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

Disposal: 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 or used containers.

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

POM-VPS

To be supplied only on veterinary prescription.

1-BZ

For animal treatment only.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4008

17. MANUFACTURER'S BATCH NUMBER

BATCH:

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 an Autoworm bolus it is good management practice to minimise worm larval contamination of the pasture by incoming animal(s). This can be achieved by dosing with Autoworm Ready Pulse at the time the animals are moved.

Where cattle have received a 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 grazing season.

† Trade Mark of Agrimin Ltd.

†† Trade Mark of Elanco products Ltd.

Trade Mark of Syntex Agribusiness Inc.

MINIMUM PARTICULARS TO APPEAR ON FOIL WRAPPING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Autoworm Finisher 6250 mg Pulsatile-release Intraruminal Device

Each bolus contains 5 tablets each containing 1250 mg of oxfendazole.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Batch:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

For oral administration.

Keep out of reach and sight of children.

For uses, dosage, contra-indications and warnings – see package leaflet.

Vm 42058/4008

POM-VPS

PACKAGE LEAFLET FOR:

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

[Batch release site not currently included]

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Autoworm Finisher 6250 mg Pulsatile-release Intraruminal Device

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

Each bolus contains 5 tablets each containing 1250 mg of oxfendazole.

4. INDICATIONS

DESIGNED FOR TURNOUT DOSING OF CATTLE IN THEIR SECOND GRAZING SEASON

A pulse release bolus device for the treatment of gastro-intestinal roundworms and lungworms, both adult and immature, and also of tapeworms, at regular intervals of approximately three weeks during a period of about fifteen weeks. THE FIRST DOSE BEING RELEASED ABOUT 3 WEEKS AFTER ADMINISTRATION. For cattle weighing between 100kg and 400 kg at time the bolus is given.

Oxfendazole is effective against inhibited/arrested larvae of *Cooperia* and usually effective against inhibited/arrested larvae of *Teladorsagia* (*Ostertagia*) in cattle. It also kills roundworm eggs.

5. CONTRAINDICATIONS

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

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

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

Do not exceed stated dose.

6. ADVERSE REACTIONS

-

7. TARGET SPECIES

Cattle weighing between 100kg and 400kg.

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

One bolus should be administered to each animal being turned out to pasture for their second grazing season and weighing between 100 and 400kg. Bodyweight should be determined as accurately as possible. Alternatively one bolus may be administered later in the grazing season – approximately three weeks before the first anthelmintic dose is normally required. 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 also sometimes develop after the active life of the bolus.

9. ADVICE ON CORRECT ADMINISTRATION

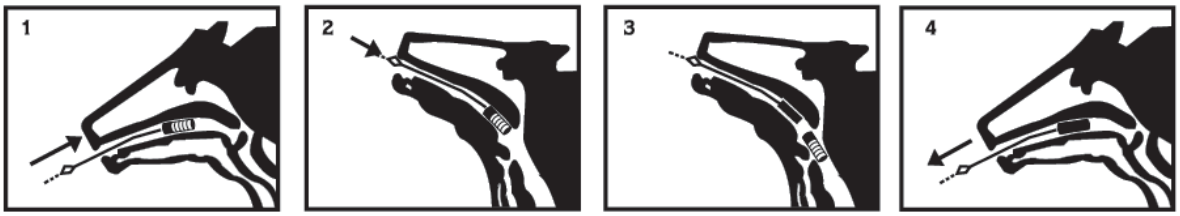
For oral use only.

Directions for use
Take time to read the instructions carefully before starting the worming session.

Give a single bolus by mouth using the Autoworm Bolus Applicator which delivers the bolus into the top of the gullet. When using the Autoworm Bolus Applicator insert the bolus into the applicator 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 pressure**. As the animal begins to swallow the end of the gun, the passage down the throat becomes easier.

At this point, the applicator is in position for firing. Squeeze the trigger to eject the bolus. **Normal care should be taken not to cause any Injury by placing the applicator 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.

Only gentle pressure should be used during bolus administration.



10. WITHDRAWAL PERIOD(S)

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

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

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

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in a dry place. Protect from frost.

12. SPECIAL WARNING(S)

Keep out of the reach and sight of children.

Further information

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.

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 selection for resistance to anthelmintics.

Worm control is best achieved when dosed animals are set stocked throughout the grazing season, or move 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 move to potentially contaminated pasture.

Where an animal(s) is to be added to a group previously treated with an Autoworm bolus it is good management practice to minimise worm larval contamination of the pasture by incoming animals.

Where cattle have received a 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 grazing season.

If lungworm vaccination is practised at turnout, then 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 become evident.

b) where dosing for liver fluke becomes necessary.

User Warnings

Wash hands after use.

For animal treatment only

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

Disposal: Dispose of any unused product or empty containers in accordance with guidance from your local waste regulation authority.

Do not contaminate ponds, waterways or ditches with the product or used containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

† Trade Mark of Agrimin Ltd

†† Trade Mark of Elanco products Ltd.

Trade Mark of Syntex Agribusiness Inc.

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1-BZ

Approved 21 August 2020