MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels.
FRONT LABEL

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, MK7 7AJ

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24, Ireland

Manufacturer responsible for batch release:
TriRx Segré
La Grindolière, Zone Artisanale, Segré
49500 Segré-en-Anjou Bleu, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zanil Fluke Drench 34 mg/ml Oral Suspension

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

Oxyclozanide

4. PHARMACEUTICAL FORM

A smooth off-white pourable suspension containing 34 mg/ml Oxyclozanide. Also contains 1.5 mg/ml methyl parahydroxybenzoate (E218) and 0.15 mg/ml propyl parahydroxybenzoate as preservatives and sodium metabisulphite (E223) 1.0 mg/ml as antioxidant.

5. PACKAGE SIZE

5 Litre

6. INDICATION(S)

For the treatment and control of chronic fasioliasis in cattle and sheep. Removes

practically all flukes (*Fasciola* spp.) present in the bile ducts of the liver.

7. CONTRAINDICATIONS

Do not use in cases of hypersensitvity to the active substance.

8. ADVERSE REACTIONS

See Back Label

9. TARGET SPECIES

For the treatment and control of chronic fasioliasis in cattle and sheep.

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

See Back Label

11. ADVICE ON CORRECT ADMINISTRATION

See Back Label

12. WITHDRAWAL PERIOD

Milk: 7 days

13. SPECIAL STORAGE PRECAUTIONS

See Back Label

14. SPECIAL WARNING(S)<User Warnings>

See Back Label

15. EXPIRY DATE

Expiry end of:

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

See Back Label

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

November 2020
Date located on Back Label

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

[Distribution category]

POM-VPS

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

For Animal Treatment Only.
Keep out of the sight and reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4595

21. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels.
BACK LABEL

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zanil Fluke Drench 34 mg/ml Oral Suspension for Cattle and Sheep

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

See Front Label

4. PHARMACEUTICAL FORM

See Front Label

5. PACKAGE SIZE

See Front Label

6. INDICATION(S)

See Front Label

7. CONTRAINDICATIONS

See Front Label

8. ADVERSE REACTIONS

At normal oxyclozanide dose levels, cattle may show slight softening of the faeces with the occasional animal showing increased frequency of defecation and transient inappetence. Milking cattle, particularly high yielders, may occasionally show a reduction in yield of 5% or more for about 48 hours after handling. The effect of this small loss may be minimised by spreading herd dosing over a period of about one week.

9. TARGET SPECIES

See Front Label

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

Give as an oral drench. Shake the product well before use. The body weight of animals should be assessed as accurately as possible before calculating the dosage. The accuracy of the dosing device should be checked.
If animals are to be treated collectively rather than individually, they should be grouped according to their body weight and dosed accordingly, in order to avoid under- or overdosing.
Drench can be given in the feed to cattle which are fed individually. Pour the recommended dose onto their concentrate ration. Molasses or salt may be added for shy feeders.
Dose according to body weight at the rate of 10 mg oxyclozanide per kg body weight for cattle and 15 mg oxyclozanide per kg body weight for sheep as follows:-

Cattle: 10 mg oxyclozanide/kg (3 ml per 10 kg)			**Sheep: 15 mg oxyclozanide/kg (4.5 ml per 10 kg)**		
Body weight	**Dose**	**Doses per pack**	**Body weight**	**Dose**	**Doses per pack**
50 kg (approx 1 cwt)	15 ml	333	10 kg (approx 22 lb)	4.5 ml	1,111
100 kg (approx 2	30 ml	166	20 kg (approx	9 ml	555
150 kg (approx 3	45 ml	111	30 kg (approx	13.5	370
200 kg (approx 4	60 ml	83	40 kg (approx	18 ml	277
250 kg (approx 5	75 ml	66	45 kg and over	20 ml	250
300 kg (approx 6	90 ml	55			
350 kg and over	105	47			

11. ADVICE ON CORRECT ADMINISTRATION

See Back Label

12. WITHDRAWAL PERIOD

See Front Label

13. SPECIAL STORAGE PRECAUTIONS

Special Storage conditions: Do not store above 25° C. Protect from light. Do not freeze.

14. SPECIAL WARNING(S)<User Warnings>

Special precautions for use in animals: At normal dose levels, oxyclozanide is not active against immature flukes present in liver tissue. The body weight of animals should be assessed as accurately as possible before calculating the dosage. The product can be given to young, pregnant and lactating animals and those in a debilitated condition (in the absence of inter current disease). Care should be taken when administering by dosing gun.

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 devise (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 pharmaceutical class and having a different mode of action should be used.

To date no resistance to oxyclozanide has been reported. Use of the 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. Due regard must always be given to physical condition, particularly of any animals in advanced pregnancy, and/or under stress from adverse weather conditions, poor nutrition, penning, handling etc.

User warnings: Do not eat, drink or smoke when using this product. Wash splashes from eyes and skin immediately. Take off any contaminated clothing immediately. User should wear chemical resistant gloves during administration of the product. Wash hands and exposed skin before meals and after work.

15. EXPIRY DATE

See Front Label

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal advice: Do not contaminate ponds, waterways or ditches with the product or used container. Harmful to aquatic life. Any unused veterinary

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

December 2020

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

[Distribution category]

See Front Label

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

See Front Label

20. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4595

21. MANUFACTURER'S BATCH NUMBER

See Front Label

OTHER INFORMATION>

Incompatibilities: In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Approved: 02 December 2020