PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle labels}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 0.1% w/v Oral Solution for Sheep

Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Moxidectin 1 mg/ml

3. PHARMACEUTICAL FORM

Oral Solution for Sheep

4. PACKAGE SIZE

1 L
2.5 L
5 L

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the treatment and control of:
Adult and immature roundworms including: Nematodirus, plus inhibited larvae of Ostertagia, Haemonchus and Trichostrongylus

Benzimidazole resistant strains of:
Ostertagia, Haemonchus, Trichostrongylus and Cooperia

ZERMEX ORAL SOLUTION has a persistent effect in preventing re-infestation by *Haemonchus contortus* and *Teladorsagia circumcincta* for 5 weeks and *Oesophagostomum columbianum* for 4 weeks after treatment.

Clinical trials have shown that ZERMEX ORAL SOLUTION is effective against certain benzimidazole (white drench) resistant strains of *Haemonchus*, *Ostertagia*, *Trichostrongylus* and *Cooperia*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

ZERMEX ORAL SOLUTION is ready-to-use. Administer 1ml per 5kg liveweight using the ZERMEX Drench Gun or any standard drenching equipment. Check dose rates and equipment before drenching commences.

READ PACKAGE LEAFLET BEFORE USE

8. WITHDRAWAL PERIOD

Meat and offal: 14 days.

Milk: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

ZERMEX ORAL SOLUTION has been shown to be safe for use in pregnant, lactating and breeding animals.

Operator warnings:
Wear protective impermeable gloves during use. Avoid direct contact with skin and eyes. In case of contact with skin and eyes wash affected area with clean water. Seek medical advice if irritation persists. Do not smoke, drink or eat while handling the veterinary medicinal product. Wash hands after use.

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

10. EXPIRY DATE

Expiry date:{month/year}

Once opened use within 6 months.

Once opened, used by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Keep container in the outer carton.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product. DANGEROUS to fish and aquatic life.

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.

FOR ANIMAL TREATMENT ONLY

3-ML

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Distributor:
Downland Marketing Limited
Main Mill
Warwick Mill Business Centre
Warwick Bridge
Carlisle
Cumbria
CA4 8RR

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4169

17. MANUFACTURER’S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 0.1% w/v Oral Solution for Sheep

Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Moxidectin 1 mg/ml

3. PHARMACEUTICAL FORM

Oral Solution

4. PACKAGE SIZE

1 L
2.5 L
5 L

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the treatment and control of:
Adult and immature roundworms including: Nematodirus, plus inhibited larvae of Ostertagia, Haemonchus and Trichostrongylus

Benzimidazole resistant strains of:
Ostertagia, Haemonchus, Trichostrongylus and Cooperia

ZERMEX ORAL SOLUTION is effective against the following parasites of sheep.

Effective against benzimidazole resistant strains of:

- *Teladorsagia circumcincta*
- *Haemonchus contortus*
- *Trichostrongylus colubriformis*
- *Cooperia curticei*

Effective against adult and immature (L4) GI worms

- *Teladorsagia circumcincta* (including inhibited larvae)
- *Ostertagia trifurcate*
- *Haemonchus contortus* (including inhibited larvae)
- *Nematodirus spathiger*
- *Nematodirus filicollis* (adults only)
- *Strongyloides papillosus* (larval stages only)
- *Cooperia curticei* (adults only)

- *Trichostrongylus axei* (including inhibited larvae)
- *Trichostrongylus colubriformis*
- *Trichostrongylus vitrinus*
- *Nematodirus battus*
- *Cooperia oncophora*
- *Oesophagostomum columbianum*
- *Oesophagostomum venulosum* (adults only)
- *Chabertia ovina*
- *Trichuris ovis* (adults only)

Effective against adult lungworm

- *Dictyocaulus filaria*

ZERMEX ORAL SOLUTION has a persistent effect in preventing re-infection by *Haemonchus contortus* and *Ostertagia circumcincta* for 5 weeks and *Oesophagostomum columbianum* for 4 weeks after treatment.

Clinical trials have shown that ZERMEX ORAL SOLUTION is effective against certain benzimidazole (white drench) resistant strains of *Haemonchus*, *Ostertagia*, *Trichostrongylus* and *Cooperia*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

ZERMEX ORAL SOLUTION is ready-to-use. Administer 1ml per 5kg liveweight using the ZERMEX Drench Gun or any standard drenching equipment. Check dose rates and equipment before drenching commences.

1ml/5kg liveweight to give a dose of 0.2mg moxidectin/kg liveweight.

Liveweight (kg)	Dose volume (ml)	Doses per Pack (1L)	Doses per Pack (2.5L)	Doses per Pack (5L)
10	2	500	1250	2500
11-15	3	333	833	1666
16-20	4	250	625	1250
21-25	5	200	500	1000
26-30	6	166	416	833
31-35	7	142	357	714
36-40	8	125	312	625
41-45	9	111	277	555
46-50	10	100	250	500
51-55	11	90	227	454
56-60	12	83	208	416
61-65	13	76	192	384
66-70	14	71	178	357
71-75	15	66	166	333

For animals over 75kg liveweight, dose at 1ml per 5kg.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days.

Milk: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

ZERMEX ORAL SOLUTION has been shown to be safe for use in pregnant, lactating and breeding animals.

Do not exceed stated dose. Do not mix with other veterinary medicinal products before administration.

Operator warnings:
Wear protective impermeable gloves during use. Avoid direct contact with skin and eyes. In case of contact with skin and eyes wash affected area with clean water. Seek medical advice if irritation persists. Do not smoke, drink or eat while handling the veterinary medicinal product. Wash hands after use.

Environmental risks have been identified for this product and special precautions apply. Read the package leaflet before use.

10. EXPIRY DATE

Expiry date: {month/year}

Once opened used within 6 months.

Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Keep container in the outer carton.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product. DANGEROUS to fish and aquatic life.

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

FOR ANIMAL TREATMENT ONLY

3-ML

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Distributor:
Downland Marketing Limited
Main Mill
Warwick Mill Business Centre
Warwick Bridge
Carlisle
Cumbria
CA4 8RR

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4169

17. MANUFACTURER’S BATCH NUMBER

Batch No:

PACKAGE LEAFLET FOR: Zermex 0.1% w/v Oral Solution for Sheep

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

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

Manufacturing site responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera Camprodon s/n – La Riba
17813 – Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZERMEX 0.1% W/V ORAL SOLUTION FOR SHEEP

Moxidectin

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

Each ml contains:

Active substance:

Moxidectin	1 mg

Excipients:

Benzyl Alcohol	40 mg
Butylated Hydroxytoluene	2.5 mg

A pale, yellow solution

4. INDICATION(S)

ZERMEX ORAL SOLUTION FOR SHEEP is a second generation macrocyclic lactone parasiticide of the milbemycin family which is effective against internal parasites of sheep. ZERMEX belongs to the avermectin/milbemycin 3-ML class of anthelmintics.

ZERMEX ORAL SOLUTION treats and controls the following parasites of sheep.

Effective against benzimidazole resistant strains of:

- *Teladorsagia circumcincta*
- *Haemonchus contortus*
- *Trichostrongylus colubriformis*
- *Cooperia curticei*

Effective against adult and immature (L4) GI worms

- *Teladorsagia circumcincta* (including inhibited larvae)
- *Ostertagia trifurcata*
- *Haemonchus contortus* (including inhibited larvae)
- *Trichostrongylus axei* (including inhibited larvae)
- *Trichostrongylus colubriformis*
- *Trichostrongylus vitrinus*
- *Nematodirus battus*
- *Nematodirus spathiger*
- *Nematodirus filicollis* (adults only)
- *Strongyloides papillosus* (larval stages only)
- *Cooperia curticei* (adults only)
- *Cooperia oncophora*
- *Oesophagostomum columbianum*
- *Oesophagostomum venulosum* (adults only)
- *Chabertia ovina*
- *Trichuris ovis* (adults only)

Effective against adult lungworm

- *Dictyocaulus filaria*

ZERMEX ORAL SOLUTION has persistent effect in preventing re-infection by *Haemonchus contortus* and *Ostertagia circumcincta* for 5 weeks and *Oesophagostomum columbianum* for 4 weeks after treatment.

5. CONTRAINDICATIONS

Do not mix with other products.

6. ADVERSE REACTIONS

-

7. TARGET SPECIES

Sheep

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

Administer 1ml per 5kg liveweight using the ZERMEX Drench Gun or any standard drenching equipment.

1ml/5kg liveweight to give a dose of 0.2mg moxidectin/kg liveweight.

Liveweight (kg)	Dose volume (ml)	Doses per Pack (1L)	Doses per Pack (2.5L)	Doses per Pack (5L)
10	2	500	1250	2500
11-15	3	333	833	1666
16-20	4	250	625	1250
21-25	5	200	500	1000
26-30	6	166	416	833
31-35	7	142	357	714
36-40	8	125	312	625
41-45	9	111	277	555
46-50	10	100	250	500
51-55	11	90	227	454
56-60	12	83	208	416
61-65	13	76	192	384
66-70	14	71	178	357
71-75	15	66	166	333

For animals over 75kg liveweight, dose at 1ml per 5kg.

9. ADVICE ON CORRECT ADMINISTRATION

ZERMEX ORAL DRENCH is ready-to-use. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; 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 bodyweight and dosed accordingly, in order to avoid under or over dosing.

Do not mix with other veterinary medicinal products before administration. Avoid the introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 14 days

Milk: 5 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C. Protect from light. Keep container in outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 6 months

When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in the 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 macrocyclic lactones has been reported in *Teladorsagia* in sheep in a number of countries. In 2008, throughout Europe, moxidectin resistance is very rare; it has been reported in a single case involving a levamisole-, benzimidazole and ivermectin-resistant strain of *Teladorsagia circumcincta*. Therefore the use of moxidectin should be based on local (regional, farm) epidemiological information about susceptibility of nematodes, local history of treatments and recommendations on how to use the product under sustainable conditions to limit further selection for resistance to anthelmintics. These precautions are especially important when moxidectin is being used to control resistant strains. Clinical trials have shown that ZERMEX ORAL SOLUTION is effective against certain benzimidazole (white drench) resistant strains of *Haemonchus*, *Ostertagia*, *Trichostrongylus* and *Cooperia*.

Symptoms of overdose generally do not occur at less than 5 times the recommended dose. They are manifested as transient salivation, depression, drowsiness and ataxia 8 to 12 hours post-treatment. Treatment is not generally necessary and recovery is generally complete within 24 to 48 hours. There is no specific antidote.

User warnings:
Wear protective impermeable gloves during use. Avoid direct contact with skin and eyes. In case of contact with skin and eyes wash affected area with clean water.

Seek medical advice if irritation persists. Do not smoke, drink or eat while handling the veterinary medicinal product. Wash hands after use.

Other precautions regarding impact on the environment:

Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance; therefore, exposure of the environment to moxidectin must be limited to the extent possible. Treatments should be administered only when necessary and should be based on faecal egg counts or evaluation of the risk of infestation at the animal and/or herd level.

Like other macrocyclic lactones, moxidectin has the potential to adversely affect non-target organisms:

- Faeces containing moxidectin excreted onto pasture by treated animals may temporarily reduce the abundance of dung feeding organisms. Following treatment of sheep with the product, levels of moxidectin that are potentially toxic to dung fly species may be excreted over a period of 4 days and may decrease dung fly abundance during that period. It has been established in laboratory tests that moxidectin may temporarily affect dung beetle reproduction; however, studies with incurred residues indicate no long-term effects. Nevertheless, in case of repeated treatments with moxidectin (as with products of the same anthelmintic class) it is advisable not to treat animals every time on the same pasture to allow dung fauna populations to recover.

- Moxidectin is inherently toxic to aquatic organisms including fish. The product should be used only according to the label instructions. Based on the excretion profile of moxidectin when administered as the oral formulation to sheep, treated animals should not have access to watercourses during the first 3 days after treatment.

Incompatibilities

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

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product. DANGEROUS to fish and aquatic life.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2022

15. OTHER INFORMATION

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

Vm 42058/4169

3-ML

Distributed in the UK by:
Downland Marketing Limited
Main Mill
Warwick Mill Business Centre
Warwick Bridge
Carlisle
Cumbria
CA4 8RR

ZERMEX ORAL SOLUTION has been shown to be safe for use in pregnant, lactating and breeding animals.

ZERMEX ORAL SOLUTION is packaged in 1, 2.5 and 5L HDPE bottles with PP screw cap closures. Not all pack sizes may be marketed.

Approved 28 July 2022