PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {500 ml label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 0.5% Pour-On Solution for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Moxidectin 5 mg/ml.

3. PHARMACEUTICAL FORM

Pour-On Solution

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment and control of: gastro-intestinal roundworms, lungworm, warbles, horn flies, mange mites and sucking and biting lice of cattle

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read entire package leaflet for full instructions before use.

1 ml per 10 kg bodyweight as a single pour-on application.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days;

Milk: 6 days (144 hours).

9. SPECIAL WARNING(S), IF NECESSARY

For full precautions refer to package leaflet.

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

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. If accidently frozen, shake vigorously before use.

Use within 6 months following the first withdrawal.

Keep the container in the outer carton.

Once opened, use by:

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

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 42058/5183

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {1, 2.5 & 5 litre labels}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 0.5% Pour-On Solution for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Moxidectin 5 mg/ml.

3. PHARMACEUTICAL FORM

Pour-On Solution

4. PACKAGE SIZE

1 Litre
2.5 Litres
5 Litres

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment and control of: gastro-intestinal roundworms, lungworm, warbles, horn flies, mange mites and sucking and biting lice of cattle

Treats and controls Gastro-intestinal roundworms (including inhibited larvae of *Ostertagia ostertagi*), lungworm (*Dictyocaulus viviparus*), warbles (*migrating larvae*), sucking and biting lice, mange mites and horn flies (*Haematobia irritans*).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read entire package leaflet for full instructions before use.

1 ml per 10 kg bodyweight as a single pour-on application.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days;

Milk: 6 days (144 hours).

9. SPECIAL WARNING(S), IF NECESSARY

For full precautions refer to package leaflet.

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

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. If accidently frozen, shake vigorously before use.

Keep the container in the outer carton.

Use within 6 months following the first withdrawal.

Once opened, use by:

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.

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

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 42058/5183

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 0.5% Pour-On Solution for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Moxidectin 5 mg/ml

3. PHARMACEUTICAL FORM

Pour-On Solution

4. PACKAGE SIZE

500 ml
1 litre
2.5 litres
5 litres

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment and control of: gastro-intestinal roundworms, lungworm, warbles, horn flies, mange mites and sucking and biting lice of cattle

Treats and controls internal and external parasites of cattle

Controls biting and sucking lice

Prevents re-infection with stomach worm for 5 weeks

Prevents re-infection with lungworm for 6 weeks

14 day meat withdrawal period

6 day (144 hour) milk withdrawal period

Safe for breeding cattle

Use in all weather conditions

Treats and controls:

Adult and larval gut roundworms:
• *Ostertagia ostertagi* (including inhibited larvae)
• *Haemonchus placei*

• *Trichostrongylus axei*
• *Nematodirus helvetianus*
• *Cooperia oncophora*
• *Cooperia punctata* (adults)
• *Oesophagostomum radiatum* (adults)
• *Bunostomum phlebotomum* (adults)

Adult lungworm:
• *Dictyocaulus viviparus*

Warbles (migrating larvae):
• *Hypoderma bovis*
• *Hypoderma lineatum*

Sucking and biting lice:
• *Linognathus vituli*
• *Haematopinus eurysternus*
• *Solenopotes capillatus*
• *Bovicola* (*Damalinia*) *bovis*

Mange mites:
• *Sarcoptes scabiei*
• *Psoroptes ovis*
• *Chorioptes bovis*

Horn flies:
• *Haematobia irritans*

ZERMEX POUR-ON contains moxidectin, a second generation macrocyclic lactone endectocide of the milbemycin family. Read entire package leaflet before use.

Treats and controls
Adult and immature gastro-intestinal roundworms (including inhibited larvae of Ostertagia ostertagi), lungworm (Dictyocaulus viviparus), warbles, sucking and biting lice, mange mites and horn flies (Haematobia irritans).

Persistent activity
ZERMEX POUR-ON SOLUTION has a persistent effect in preventing re-infestation by Ostertagia ostertagi for 5 weeks and Dictyocaulus viviparus for 6 weeks after a single dose.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour onto skin at the rate of 1ml per 10kg bodyweight. Pour along the midline of the back of the animal from the withers to the tailhead. Apply to clean, healthy areas of skin. All cattle in the same group should be treated.

Example:

Liveweight kg	Dose Volume ml	Doses Per Pack (500 ml)	Doses Per Pack (1 litre)	Doses Per Pack (2.5 litre)	Doses Per Pack (5 litre)
100	10	50	100	250	500
150	15	33	66	166	332
200	20	25	50	125	250
250	25	20	40	100	200
300	30	16	33	83	166
350	35	14	28	71	142
400	40	12	25	62	125
450	45	11	22	55	111
500	50	10	20	50	100
550	55	9	18	45	90
600	60	8	16	41	83

Over 600 kg liveweight, give 1 ml per 10 kg liveweight.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days;

Milk: 6 days (144 hours).

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings
Avoid direct contact with skin and eyes. If splashed in the eye or on the skin, wash with plenty of clean, running water immediately. Seek medical advice if irritation persists.

Wear protective clothes and impermeable gloves when applying the product.

Do not eat, drink or smoke whilst handling the 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:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from light.

Keep container in the outer carton.

If accidentally frozen, shake vigorously before use.

Use within 6 months following the first withdrawal.

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 42058/5183

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PACKAGE LEAFLET FOR:
ZERMEX 0.5% w/v POUR-ON SOLUTION FOR CATTLE

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 0.5% w/v POUR-ON SOLUTION FOR CATTLE

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

Solution containing: 5 mg/ml moxidectin, 0.1 mg/ml butylated hydroxyanisole and 0.03 mg/ml tert butyl hydroquinone

Pale yellow oily solution.

4. INDICATION(S)

Treats and controls:

Adult and larval gut roundworms:
• *Ostertagia ostertagi* (including inhibited larvae)
• *Haemonchus placei*
• *Trichostrongylus axei*
• *Nematodirus helvetianus*
• *Cooperia oncophora*
• *Cooperia punctata* (adults)
• *Oesophagostomum radiatum* (adults)
• *Bunostomum phlebotomum* (adults)

Adult lungworm:
• *Dictyocaulus viviparus*

Warbles (migrating larvae):
• *Hypoderma bovis*
• *Hypoderma lineatum*

Sucking and biting lice:
• *Linognathus vituli*
• *Haematopinus eurysternus*
• *Solenopotes capillatus*
• *Bovicola* (*Damalinia*) *bovis*

Mange mites:
• *Sarcoptes scabiei*
• *Psoroptes ovis*
• *Chorioptes bovis*

Horn flies:
• *Haematobia irritans*

Persistent activity
ZERMEX POUR-ON SOLUTION has a persistent effect in preventing re-infestation by *Ostertagia ostertagi* for 5 weeks and *Dictyocaulus viviparus* for 6 weeks after a single dose.

5. CONTRAINDICATIONS

Not to be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

6. ADVERSE REACTIONS

Reactions at the site of application may occur after application in very rare occasions.

Neurological signs (including ataxia, trembling and lethargy) have been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

For external use only.

1 ml per 10 kg bodyweight (based on a recommended dose rate of 0.5 mg moxidectin per kg bodyweight) as a single POUR-ON SOLUTION application. Pour along the midline of the back of the animal from the withers to the tailhead. Apply to clean, healthy areas of skin. All cattle in the same group should be treated.

Use the following table as a guide:

Bodyweight (kg)	Dose Volume (ml)
100	10
150	15
200	20
250	25
300	30
350	35
400	40
450	45
500	50
550	55
600	60

For cattle weighing over 600 kg bodyweight, dose at 1 ml per 10 kg.

9. ADVICE ON CORRECT ADMINISTRATION

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.

The 500 ml and 1 litre containers have a dosing chamber graduated up to 600 kg bodyweight. To use, unscrew the cap of the chamber and take the cover off. To fill the chamber, press the main part of the container until the product reaches the required level in the chamber. Pour along the midline of the back of the animal, from the withers to the tailhead until the chamber is empty.

The use of a multi-dosing POUR-ON SOLUTION gun is recommended for the 2.5 litre and 5 litre containers.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 14 days;

Milk: 6 days (144 hours).

11. SPECIAL STORAGE PRECAUTIONS

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

Keep container in the outer carton.

Shelf-life after first opening the container: 6 months.

If accidentally frozen, shake vigorously before use.

Not to be mixed with other veterinary medicinal products before application.

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.

Keep out of the sight and reach of children

12. SPECIAL WARNING(S)

ZERMEX POUR-ON SOLUTION has been shown to be safe for use in pregnant, lactating and breeding cattle.

To avoid possible secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer ZERMEX POUR-ON SOLUTION at the end of the period of warble fly activity and before the larvae reach their resting sites. Consult your veterinary surgeon on the correct timing of treatment.

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.

To date, no resistance to moxidectin in cattle parasites has been reported. The use of this product should be based on local (regional, farm) epidemiological information about susceptibility of the nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

User Warnings
Avoid direct contact with skin and eyes. If splashed in the eye or on the skin, wash with plenty of clean, running water immediately. Seek medical advice if irritation persists.

Wear protective clothes and impermeable gloves when applying the product.

Do not eat, drink or smoke whilst handling the 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 cattle with the product, levels of moxidectin that are potentially toxic to dung fly species may be excreted over a period more than 2 weeks 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, field studies 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 pour-on formulation, treated animals should not have access to watercourses during the first week after treatment.

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.

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

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

For animal treatment only

POM-VPS

To be supplied only on veterinary prescription.

Vm 42058/5183

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

ZERMEX POUR-ON SOLUTION is available in 500 ml and 1 litre fluorinated polyethylene packs with a squeeze-measure-pour system or 2.5 and 5 litre fluorinated polyethylene backpacks.

ZERMEX POUR-ON SOLUTION is an endectocide active against a wide range of internal and external parasites of cattle.

It contains moxidectin, a second generation macrocyclic lactone of the milbemycin family. Moxidectin paralyses and kills parasites by its effect on their nervous systems.

Moxidectin is rapidly absorbed following ZERMEX POUR-ON SOLUTION application.

It is distributed throughout the body tissues for a rapid effect on parasites and reaches highest concentrations in fat from which it is slowly released back into the circulation. It is this “slow release” dose over a long period of time which is active against worms picked up by the cattle after dosing.

ZERMEX POUR-ON SOLUTION is ideal for parasite control in cattle

• Effective against important internal and external parasites

• Safe for breeding cattle

• Long persistent activity against stomach worm and lungworm means:

• 14 day meat withdrawal period

• 6 day (144 hour) milk withdrawal period

Gavin Hall

Approved: 14 January 2025