PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {50 ml label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 1% w/v Solution for Injection for Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Moxidectin 10 mg/ml

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Sheep

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Meat & offal: 70 days.

Milk: not for use in sheep producing milk for human consumption or industrial purposes, including the dry period.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in animals vaccinated against footrot.

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

10. EXPIRY DATE

EXP (printed on bottle)

11. SPECIAL STORAGE CONDITIONS

Keep container in outer carton.

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

-

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 42058/4171

17. MANUFACTURER'S BATCH NUMBER

Lot (printed on bottle)

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {200 & 500 ml label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 1% w/v Solution for Injection for Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 10 mg/ml moxidectin

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

200 ml
500 ml

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the prevention and treatment of Sheep Scab

For the treatment and control of Adult and immature roundworms and nasal bots.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection. Read package leaflet before use.

8. WITHDRAWAL PERIOD

Meat & offal: 70 days.

Milk: not for use in sheep producing milk for human consumption or industrial purposes, including the dry period.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in animals vaccinated against footrot.

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

10. EXPIRY DATE

EXP.:

11. SPECIAL STORAGE CONDITIONS

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

Keep container in 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

Read package leaflet for full disposal advice.

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4171

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 1% w/v Solution for Injection for Sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 10 mg/ml moxidectin

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml
200 ml
500 ml

5. TARGET SPECIES

Sheep

6. INDICATION(S)

For the prevention and treatment of Sheep Scab

For the treatment and control of Adult and immature roundworms and nasal bots.

For the prevention and treatment of Scab (psoroptic mange). For the treatment and control of gastro-intestinal roundworms, lungworm and nasal bots of sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

0.1ml per 5kg bodyweight by subcutaneous injection in the neck. Determine sheep weight to ensure correct dose rate is used.

READ PACKAGE LEAFLET BEFORE USE.

Routine Scab Prevention
One injection at the recommended dosage will protect against Psoroptes ovis (scab mites) infestation for at least 28 days.

Treatment of Scab Outbreaks
Two injections at the recommended dosage. 10 days apart. The two injections must be given on different sides of the neck.

Treatment of Scab
• The signs of scab can be confused with those of the chewing louse *Bovicola*

(Damalinia) ovis. As with other available endectocides ZERMEX is not effective against chewing lice. Consult your veterinary surgeon to ensure correct diagnosis.

• Inject all sheep in the affected flock or sub-flock twice 10 days apart.

• The two injections must be given on different sides of the neck.

• It is important to ensure that all in-contact sheep are treated.

• Sheep scab mites can remain infective off the animal, on fences, posts etc. for at least 16 days. Since ZERMEX protects for 28 days (i.e longer than the time for which scab mites can survive off the animal), treated sheep can be immediately turned back onto the same pasture after dosing.

• Since the effect of any injectable on scab mites is not immediate, contact between treated infected sheep and non-treated, non-infected sub flocks must be avoided until at least 12 days after the last treatment.

Prevention of scab

• For routine prevention all sheep in the flock must be injected once.

• A single injection with ZERMEX will protect against sheep scab for 28 days from the time of treatment. If treated sheep come in contact with infested animals after that time, infestation can occur.

• All brought-in or returned animals should be treated and isolated for 12 days before mixing with the rest of the flock.

• Ensure adequate fencing between neighbouring flocks.

Treatment & Control of Worms

For advice see package leaflet

8. WITHDRAWAL PERIOD

Meat & offal: 70 days.

Milk: not for use in sheep producing milk for human consumption or industrial purposes, including the dry period.

9. SPECIAL WARNING(S), IF NECESSARY

For user warnings see packet leaflet.

Do not use in animals vaccinated against footrot.

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.

Following withdrawal of the first dose, use within 6 months. Discard unused product

Vial must not be broached more than 10 times.

Keep container in 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. 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

50 ml	Treats 50 x 50 kg sheep
200 ml	Treats 200 x 50 kg sheep
500 ml	Treats 500 x 50 kg sheep

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4171

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET FOR: Zermex 1% w/v Solution for Injection 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 1% w/v Solution for Injection for Sheep

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

Contains: 10 mg/ml moxidectin, 40 mg/ml Benzyl Alcohol and 2.5 mg/ml Butylated Hydroxytoluene.

A clear to pale yellow aqueous solution

4. INDICATION(S)

ZERMEX 1% w/v Solution for Injection for Sheep is an endectocide active against internal and external parasites in sheep. It contains moxidectin, a second generation macrocyclic lactone of the milbemycin family. Moxidectin is rapidly absorbed following subcutaneous injection (under the skin). 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” over a long period of time which is active against parasites picked up by sheep after dosing.

ZERMEX 1% w/v Solution for Injection for Sheep is effective against the following internal and external parasites of sheep.

Gastro-intestinal roundworms: *Haemonchus contortus*, *Teladorsagia circumcincta* (including inhibited larvae), *Trichostrongylus axei* (adults), *Trichostrongylus*

colubriformis (adults and L3), *Cooperia curticei* (adults), *Nematodirus spathiger* (adults), *Cooperia punctata* (adults), *Gaigeria pachyscelis* (L3), *Oesophagostomum columbianum* (L3), *Chabertia ovina* (adults).

Adult lungworm: *Dictyocaulus filaria*

Larvae of nasal bots: *Oestrus ovis* (L1, L2, L3)

Mange (scab) mites: *Psoroptes ovis*

ZERMEX 1% w/v Injectable Solution for Sheep has a persistent effect in preventing infection or re-infection for:
• at least 4 weeks against *Psoroptes ovis* (scab mites)
• 5 weeks against *Teladorsagia circumcincta* and *Haemonchus contortus*
• 4 weeks against *Gaigeria pachyscelis* and *Oesophagostomum columbianum*
• 2 weeks against *Trichostrongylus colubriformis*

5. CONTRAINDICATIONS

Do not use in animals vaccinated against footrot.

6. ADVERSE REACTIONS

ZERMEX 1% Solution for injection for Sheep has a wide margin of safety and symptoms of overdose do not generally occur at less than 10 times the recommended dose. Signs are manifested as transient salivation, depression, drowsiness and ataxia 8 and 12 hours post-treatment. No treatment is generally necessary. The symptoms resolve in 24 to 48 hours. There is no specific antidote.

Extensive studies in laboratory animals and cattle have shown no adverse effects during pregnancy. There are no known interactions with other animal health products used routinely in sheep such as mineral supplements, fluke or worm treatments, or clostridial vaccines. However, there have been isolated reports of adverse reactions in sheep that have previously received footrot vaccination.

7. TARGET SPECIES

Sheep

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

For subcutaneous use only. Read package leaflet before use.

Dose rate: 0.1 ml per 5kg bodyweight (based on a recommended dose rate of 0.2mg moxidectin per kg bodyweight) administered by subcutaneous injection in the neck.

Use the following table as a guide:

BODYWEIGHT (KG)	DOSE VOLUME (ML)	SINGLE DOSES PER PACK		
		50 ml	200 ml	500 ml
20	0.4	125	500	1,250
25	0.5	100	400	1,000
30	0.6	83	333	833
40	0.8	62	250	625
50	1.0	50	200	500
60	1.2	41	166	416
70	1.4	35	142	357
80	1.6	31	125	312

For sheep less than 20 kg bodyweight or over 80 kg bodyweight, dose at 0.1 ml per 5 kg.

9. ADVICE ON CORRECT ADMINISTRATION

Use sterile 18 gauge needles or smaller, of half inch (1.5 cm) length. Ensure that the needle is inserted carefully under the skin using aseptic precautions and that the product does not leak from the injection site. Be certain that the needle has penetrated the skin before delivering the dose. 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 UNDERDOSE. As with any scab treatment, underdosing can cause suppression and spread of the disease. When treating groups of animals, use only the ZERMEX Automatic Injector and vented draw-off system. For the treatment of individual sheep, a syringe not exceeding 2.5 ml and calibrated in increments of 0.1 ml should be used. Syringes must be filled from the vial through a dry, sterile draw-off needle that has been placed in the vial stopper. Vial stoppers must not be broached more than 10 times.

Prevention of Scab

• For routine prevention, all sheep in the flock must be injected once.
• A single injection with ZERMEX will protect against sheep scab for at least 28 days from the time of treatment. If treated sheep come in contact with infected animals after that time, infestation can occur.
• All brought-in or returned animals should be treated and isolated for 12 days before mixing with the rest of the flock.
• Ensure adequate fencing between neighbouring flocks.

Treatment of Scab Outbreaks

• The signs of scab can be confused with those of chewing louse *Bovicola* (*Damalinia*) *ovis*. As with other available endectocides ZERMEX is not effective against chewing lice. Consult your veterinary surgeon to ensure correct diagnosis.
• Inject all sheep in the affected flock or sub-flock twice, 10 days apart.
• The two injections must be given on different sides of the neck.

• It is important to ensure that all in-contact sheep are treated.
• Sheep scab mites can remain infective off the animal, on fences posts etc. for at least 16 days. Since ZERMEX protects for at least 28 days (i.e. longer than the time for which scab mites can survive off the animal), treated sheep can be immediately turned back onto the same pasture after dosing.
• Since the effect of any injection on scab mites is not immediate, contact between treated infected sheep and non-treated, non-infected sub-flocks must be avoided until at least 12 days after the last treatment.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 70 days.

Milk: Not for use in sheep producing milk for human consumption or industrial purposes, including the dry period.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Following withdrawal of the first dose, use the product within 6 months.

Discard unused product. Keep container in outer carton.

When the container is broached 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/carton.

Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Not to be mixed with other veterinary medicinal products before administration

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 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. Trials have shown that ZERMEX 1% w/v Solution for Injection for Sheep may be effective against strains of *Haemonchus contortus* resistant to benzimidazoles (white drenches), ivermectin and doramectin.

User Warnings:
Care should be taken to avoid self-injection.

In case of contact with skin and eyes wash affected area with clean water.

Do not smoke, eat or drink while handling the product.

Wash hands after use.

Advice to medical practitioners: in cases of accidental self-injection treat any specific signs symptomatically.

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, in particular aquatic organisms and dung fauna.

- 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 more than 4 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, 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 injectable formulation to sheep, treated animals should not have access to watercourses during the first 11 days 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. 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

March 2021

15. OTHER INFORMATION

For animal treatment only

ZERMEX 1% w/v Solution for Injection for Sheep is available in high density polyethylene containers of 50, 200 and 500 ml. Not all pack sizes may be marketed.

POM-VPS

To be supplied only on veterinary prescription

Vm 42058/4171

3-ML

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

Telephone 01228 564498

Treatment and Control of Worms
ZERMEX is a member of the avermectin/milbemycin 3-ML class of anthelmintics. The advice of a veterinary surgeon should be sought in using ZERMEX 1% w/v Solution for Injection for Sheep in a dosing programme, to ensure correct diagnosis of the nematode infection present and to minimise the risk of developing resistance.

Some facts about sheep scab
What is sheep scab?

It is a highly contagious form of mange caused by the tiny mite *Psoroptes ovis* which can infest sheep of all ages and breeds.

What are the signs of scab?
Scab mites cause intense irritation. Early signs include foot stamping, rubbing against fence posts, scratching with the hind legs and wool pulling. Eventually, considerable wool loss occurs and bare patches of inflamed skin appear that leak tissue fluid which forms scabs. Consult your vet if in any doubt over the diagnosis.

What are the effects of scab on production?
A scab outbreak can cause severe reduction in growth rate, reduced wool clip, damage to the hide and up to a third of those infested can die. Lambs from infested ewes have lower birth weights.

How can it spread?

1. Brought-in sheep
70% of outbreaks are caused by brought-in sheep. Pens at markets that have contained infested sheep can harbour mites which can infest sheep subsequently placed in the pen.

Sheep mixed with or alongside infested animals can become infested.

2. Transported sheep
Scab mites can survive and remain infective on wool left in livestock lorries and trailers for some time.

3. Borrowed tups
Any animal entering your farm can bring scab with it and be a risk to your flock.

4. Shared grazing
It is essential all sheep are gathered for treatment and that none are missed which could subsequently re-infest treated sheep.

5. Inadequate fencing
Poor fencing may allow sheep to stray onto or from a neighbouring farm and cause a scab outbreak in your flock.

6. Shearing equipment
Shearing combs and cutters and contaminated clothing can spread scab.

The benefits of a long-acting product for scab prevention and treatment
Longer duration of protection from infestation
If treated sheep inadvertently come into contact with scab mites after dosing from, for example, untreated brought-in sheep, they will be protected from infestation for at least 28 days.

Sheep can be returned to infested pasture after dosing

Since ZERMEX protects for at least 28 days (i.e. longer than the time for which scab mites can survive off the animal), treated sheep can be immediately turned back onto the same pasture after dosing.

Approved: 23/03/21