LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{1 x 50 ml / 1 x 200 ml}
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
200 ml HDPE vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 100 mg/ml LA Solution for Injection for Cattle
Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Moxidectin	100 mg
Benzyl Alcohol (E1519)	70 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml
Treats 20 x 250 kg cattle
200 ml
Treats 80 x 250 kg cattle

5. TARGET SPECIES

Refer to section 6.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage rate: 0.5 ml/50 kg bodyweight to give 1 mg moxidectin/kg bodyweight. Determine cattle weight to ensure correct dose rate is used. Do not overdose. Do not use in animals less than 100 kg or more than 500 kg bodyweight.

Read the package leaflet before use.
To be administered by a single subcutaneous injection in the dorsal (outer) surface of the ear.
Shake vigorously before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 108 days.
Milk: Not permitted for use in lactating animals producing milk for human consumption or industrial purposes or within 80 days of expected parturition.

The withdrawal period is based solely on a single injection at the ear site of injection.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year} DD/MMM/YY
Shelf-life after first opening the container: 28 days.
Once broached/opened, use by: …/…/…"

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Keep the container in the outer carton in order to protect from light.

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

Extremely dangerous for fish and aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4172

17. MANUFACTURER'S BATCH NUMBER

Batch{number}:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 100 mg/ml LA Solution for Injection for Cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Moxidectin	100 mg
Benzyl Alcohol (E1519)	70 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml
Treats 20 x 250 kg cattle

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
To be administered by a single subcutaneous injection in the dorsal (outer) surface of the ear.
Shake vigorously before use.

5. WITHDRAWAL PERIOD(S)

Meat and offal: 108 days.
Milk: Not permitted for use in lactating animals producing milk for human consumption or industrial purposes or within 80 days of expected parturition.

6. BATCH NUMBER

Batch {number}:

7. EXPIRY DATE

EXP {month/year} DD/MMM/YY
Shelf life after first broaching the vial: 28 days.
Once broached, use by: …/…/…'

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Zermex 100 mg/ml LA Solution for Injection for Cattle

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

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

Manufacturer for the batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermex 100 mg/ml LA Solution for Injection for Cattle

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Solution for injection containing 100 mg/ml moxidectin (active ingredient) and 70 mg/ml Benzyl Alcohol (E1519, preservative/co-solvent). Clear yellow liquid**.**

4. INDICATION(S)

This product is a long acting 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 absorbed following subcutaneous injection with maximum blood concentrations being achieved 24 - 48 hours post injection. Blood levels persist for a time then slowly decline to provide prolonged protection against infection or re-infection.
Moxidectin is distributed through-out the body tissues for a rapid effect on parasites and reaches highest concentrations in the fat from which it is slowly released back into the circulation.

The product is effective in the treatment and prevention of lungworm and gastro-intestinal nematodes and certain arthropod parasites of cattle.

Treats and controls
The product effectively controls infections of the following parasites present at the time of treatment:

- Adult and immature gastro-intestinal nematodes:
. *Haemonchus placei*
. *Haemonchus contortus*
. *Ostertagia ostertagi* (including inhibited larvae)
. *Trichostrongylus axei*
. *Trichostrongylus colubriformis*
. *Nematodirus helvetianus* (adults only)
. *Nematodirus spathiger*
. *Cooperia surnabada*
. *Cooperia oncophora*
. *Cooperia pectinata*
. *Cooperia punctata*
. *Oesophagostomum radiatum*
. *Bunostomum phlebotomum* (adults only)
. *Chabertia ovina* (adults only)
. *Trichuris spp.* (adults only)

- Adult and immature respiratory tract nematode
. *Dictyocaulus viviparus*

- Warble grubs (migrating larvae):
. *Hypoderma bovis*
. *Hypoderma lineatum*

- Lice
. *Linognathus vituli*
. *Haematopinus eurysternus*
. *Solenopotes capillatus*
. *Bovicola bovis* (aid in control)

- Mange mites
. *Sarcoptes scabiei*
. *Psoroptes ovis*
. *Chorioptes bovis* (aid in control)

The product also provides long-lasting protection of cattle against infection or re-infection with the following parasites for the period indicated:

Species	**Protection period (days)**
Dictyocaulus viviparus	120
Ostertagia ostertagi	120
Haemonchus placei	90
Oesophagostomum radiatum	150
Trichostrongylus axei	90
Linognathus vituli	133

Persistent efficacy periods have not been established for parasite species other than those included in the above list. Therefore, reinfection of animals on the pasture contaminated by parasites other than these remains possible before the end of the 90 day minimum persistency period demonstrated for specific species.

5. CONTRAINDICATIONS

Do not use in animals less than 100 kg bodyweight or greater than 500 kg.
Do not inject the product by intravascular route. Intravascular injection may result in ataxia, paralysis, convulsions, collapse and death. To prevent any intravascular injection, carefully follow the administration procedure described in item “Dosage for each species, routes and method of administration.”

6. ADVERSE REACTIONS

On rare occasions, immediate or delayed swelling can be observed at the injection site, these swellings may further develop into abscesses (approx. 1% of cases). The frequency of injection site swellings tends to be higher in the heavier animals. These side effects generally disappear without treatment, within 14 days after administration, some may persist for up to 5 weeks in a number of animals (<5%) and in very rare occasions longer.

On rare occasions, depression and ataxia can be observed after injection.
In case of hypersensitivity reactions, a symptomatic treatment should be applied.

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 side 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 AND METHOD OF ADMINISTRATION

Dosing Guidelines
Due to the long-lasting protection against lungworm (*Dictyocaulus viviparus*) and stomach worms (*Ostertagia ostertagi* and *Haemonchus placei*), a single treatment with the product at turn-out helps control parasitic bronchitis (lungworm) and parasitic gastro-enteritis throughout the grazing season by reducing the build-up of infective larvae on pasture associated with these parasites. For best results the injection should be given to each calf of target weight to be grazed together immediately prior to being turned out to pasture. Animals should be set stocked throughout the grazing season or moved to a pasture which has not been grazed by other cattle earlier in the season.

Dosage and Administration
Dose rate: 0.5 ml/50 kg bodyweight to give 1 mg moxidectin/kg bodyweight.
As a guide, use the following dosing schedule:

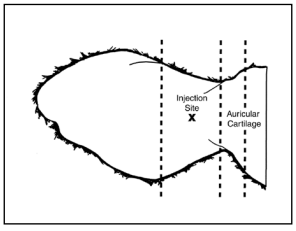
Bodyweight in kg	Dose volume in ml
100	1.0
150	1.5
200	2.0
250	2.5
300	3.0
350	3.5
400	4.0
450	4.5
500	5.0

Determine cattle weight to ensure correct dose rate is used. Do not overdose. Do not use in animals less than 100 kg or more than 500 kg bodyweight.

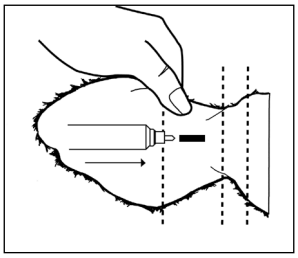
The product should be administered by a single subcutaneous injection in the ear using an 18 gauge x 25-40 mm hypodermic needle. Any single dose syringe may be used with the
50 ml bottle. The 50ml vial stoppers must not be broached more than 20 times. Use automatic syringe equipment for the 200 ml bottle. The dorsal (outer) surface of the ear should first be cleansed with
antiseptic and allowed to briefly air dry. The injection should be given subcutaneously in the loose skin on the dorsal (outer) surface of the ear, just distal to (i.e. slightly away from) the edge of the ear cartilage (see diagram). To accomplish this, feel for the edge of the ear cartilage closest to the head, on the dorsal (outer) surface of the ear. From this landmark, taking care to avoid blood vessels
(artery, vein), the needle is inserted subcutaneously starting at a point approximately 3 to 3.5 centimetres distal (away from the head), and directed towards the base of the ear. Advance the
needle to the hub, then gently aspirate (pull back the plunger of) the syringe to confirm that the needle is not in a blood vessel. Upon injection, the resulting depot of injected material should end up a slight distance away from the edge of the ear cartilage. Following administration, the needle is withdrawn from the skin as pressure is applied for several seconds with the thumb at the point of insertion.

Shake vigorously before use.

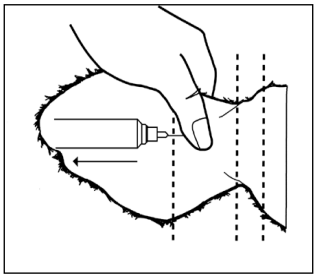
Diagram: Ear injection procedure



- The injection site is approximately 3.5 cm (1.5 inches) distal to the distal edge of the auricular cartilage.



- Use one hand to grasp and steady the ear.
- Inject subcutaneously using an 18 gauge x 1 inch needle.



- Inject contents. Depot should be just distal to the distal edge of the auricular cartilage.
- Apply pressure at the point of insertion as the needle is withdrawn from the skin to help seal the opening.

9. ADVICE ON CORRECT ADMINISTRATION

To prevent abscesses, strict aseptic technique is recommended.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 108 days.
Milk: Not permitted for use in lactating animals producing milk for human consumption or industrial purposes or within 80 days of expected parturition.

The withdrawal period is based solely on a single injection at the ear site of injection.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 ºC. Keep the container in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container:: 28 days.
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 worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNINGS

The product is effective against Hypoderma larvae at the time of treatment but its persistent activity against Hypoderma has not been evaluated. If the product is given before the end of the fly season complimentary treatment with a product effective against Hypoderma may be required.

To avoid possible incidence of secondary reactions by the death of Hypoderma larvae in the spine or the oesophagus of animals, it is recommended to administer this product after the end of the fly activity and before the larvae reach their resting sites.

Immunity to nematodes depends on adequate exposure to infection. Although not normally the case, circumstances could occur in which anthelmintic control measures might increase the vulnerability of cattle to re-infection. Animals may be at risk towards the end of their first grazing season, particularly if the season is long, or in the following year if they move onto heavily contaminated pasture. In such instances, further control measures may be necessary.

Operator warning: Avoid direct contact with skin and eyes. Do not smoke, drink or eat while handling this product. Wash hands after use.
Take care to avoid self-injection. Advice to Medical Practitioners: in cases of accidental self injection treat any signs symptomatically.

Special precautions for use in animals:

The product has been shown to be safe for use in pregnant animals.
The product has been formulated specifically for subcutaneous injection in the dorsal (outer) surface of the ear of cattle and must not be given by any other route of administration or to any other species.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Interaction with other medicinal products and other forms of interaction:

No known incompatibility with concurrent administration of mineral supplements, fluke treatments or vaccines.

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 cattle 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, 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. This implies that when allowing moxidectin to enter water bodies, this may have a severe and lasting impact on aquatic life. To mitigate this risk, the product should be used only according to the label instructions. Based on the excretion profile of moxidectin when administered as the injectable formulation, treated animals should not have access to watercourses during the first 10 days after treatment.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, 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. Extremely dangerous for fish and aquatic organisms.

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

15. OTHER INFORMATION

For animal treatment only.

Presentations to be sold:
- Box containing 1 vial of 50ml size
- Box containing 1 vial of 200ml size

Not all pack sizes may be marketed.

Approved 22 October 2019