

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box for 0.5L HDPE container**

**Box for 1L HDPE container**

**Box for 2.5L HDPE container**

**Box for 5L HDPE container**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

ZERMEX 5 mg/ml Pour-On Solution for Cattle

MOXIGRO 5 mg/ml Pour-On Solution for Cattle

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains:

Active Substances:

Moxidectin 5.00 mg

Excipients:

Butylated hydroxyanisole E320 0.10 mg

Tert butyl hydroquinone 0.03 mg

**3. PHARMACEUTICAL FORM**

Pour-on solution

A pale yellow oily liquid

**4. PACKAGE SIZE**

0.5 L

1L

2.5L

5L

**5. TARGET SPECIES**

Cattle

**6. INDICATION(S)**

Infections of cattle with parasites sensitive to moxidectin.

For the treatment of infections caused by:

**- Adult and larval gastro-intestinal nematodes:**

*Haemonchus placei*

*Ostertagia ostertagi* (including inhibited larvae)

*Trichostrongylus axei*

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

**- Adult respiratory tract nematode**

*Dictyocaulus viviparus*

**- Warbles (migrating larvae)**

*Hypoderma bovis*  
*Hypoderma lineatum*

**- Lice**

*Linognathus vituli*  
*Haematopinus euryesternus*  
*Solenopotes capillatus*  
*Bovicola bovis* (*Damalinia bovis*)

**- Mange Mites**

*Sarcoptes scabiei*  
*Psoroptes ovis*  
*Chorioptes bovis*

**- Horn Flies**

*Haematobia irritans*

The product has a persistent effect in preventing against reinfection by:

*Ostertagia ostertagi* for 5 weeks  
*Dictyocaulus viviparus* for 6 weeks

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For pour-on use. Read the package leaflet before use. The product should be administered at a dose rate of 0.5 mg moxidectin/kg body weight (1 ml for 10 kg) and as a single pour-on application.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Meat and offal : 14 days.  
Milk: 6 days (144 hours).

**9. SPECIAL WARNING(S), IF NECESSARY**

User warnings:

- Do not smoke, eat or drink while handling the product.
- Avoid direct contact with skin and eyes.

- Wash hands after use.
- Protective clothes and gloves are recommended when using the product.
- If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.

**10. EXPIRY DATE**

EXP {month/year}

After first opening, use the product within 6 months.

Once opened, use by: ".../.../..."

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C

Protect from light

If accidentally frozen, shake vigorously before use.

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

The product can be toxic for fish and aquatic organisms.

Avoid spillage directly into water courses.

Any unused product or waste material should be disposed of in accordance with national requirements.

**13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only.

To be supplied only on veterinary prescription.

**14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"**

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Zoetis subsidiaries in EU member states

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**LABEL 0.5L HDPE container**

**LABEL 1L HDPE container**

**LABEL 2.5L HDPE container**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

ZERMEX 5 mg/ml Pour-On Solution for cattle

MOXIGRO 5 mg/ml Pour-On Solution for Cattle

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each ml contains:

Active Substances:

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Excipients:

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Tert butyl hydroquinone 0.03 mg

**3. PHARMACEUTICAL FORM**

Pour-on solution

A pale yellow oily liquid

**4. PACKAGE SIZE**

0.5 L

1L

2.5L

5L

**5. TARGET SPECIES**

Cattle

**6. INDICATION(S)**

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For the treatment of infections caused by:

**- Adult and larval gastro-intestinal nematodes:**

*Haemonchus placei*

*Ostertagia ostertagi* (including inhibited larvae)

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

**- Adult respiratory tract nematode**

*Dictyocaulus viviparus*

**- Warbles (migrating larvae)**

*Hypoderma bovis*  
*Hypoderma lineatum*

**- Lice**

*Linognathus vituli*  
*Haematopinus euryesternus*  
*Solenopotes capillatus*  
*Bovicola bovis* (*Damalinia bovis*)

**- Mange Mites**

*Sarcoptes scabiei*  
*Psoroptes ovis*  
*Chorioptes bovis*

**- Horn Flies**

*Haematobia irritans*

The product has a persistent effect in preventing against reinfection by:

*Ostertagia ostertagi* for 5 weeks

*Dictyocaulus viviparus* for 6 weeks

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For pour-on use. Read the package leaflet before use. The product should be administered at a dose rate of 0.5 mg moxidectin/kg body weight (1 ml for 10 kg) and as a single pour-on application.

Read the package leaflet before use.

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Meat and offal : 14 days.

Milk: 6 days (144 hours).

**9. SPECIAL WARNING(S), IF NECESSARY**

User warnings:

- Do not smoke, eat or drink while handling the product.
- Avoid direct contact with skin and eyes.

- Wash hands after use.
- Protective clothes and gloves are recommended when using the product.
- If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.

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EXP {month/year}

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Once opened, use by: ".../.../..."

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**13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only.

To be supplied only on veterinary prescription.

**14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"**

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Pfizer/Zoetis subsidiaries in EU member states

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**B. PACKAGE LEAFLET**



**PACKAGE LEAFLET**  
**ZERMEX 5 mg/ml 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**

**Marketing authorisation holder:**

Zoetis subsidiaries in the EU member states

**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 5 mg/ml Pour-On Solution for cattle  
MOXIGRO 5 mg/ml Pour-On Solution for Cattle

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

Each ml contains:

Active Substances:

Moxidectin 5.00 mg

Excipients:

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**4. INDICATION(S)**

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For the treatment of infections caused by:

**- Adult and larval gastro-intestinal nematodes:**

*Haemonchus placei*

*Ostertagia ostertagi* (including inhibited larvae)

*Trichostrongylus axei*

*Nematodirus helvetianus*

*Cooperia oncophora*

*Cooperia punctata* (adults)

*Oesophagostomum radiatum* (adults)  
*Bunostomum phlebotomum* (adults)

**- Adult respiratory tract nematode**

*Dictyocaulus viviparus*

**- Warbles (migrating larvae)**

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*Chorioptes bovis*

**- Horn Flies**

*Haematobia irritans*

The product has a persistent effect in preventing against reinfection by:

*Ostertagia ostertagi* for 5 weeks

*Dictyocaulus viviparus* for 6 weeks

## 5. CONTRAINDICATIONS

None known.

## 6. ADVERSE REACTIONS

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Cattle.

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

The product should be administered at a dose rate of 500 µg moxidectin/kg body weight (1 ml for 10 kg) as a single topical application.

To be administered along the midline of the back of the animal from the withers to the tailhead.

Apply to clean healthy skin.

**9. ADVICE ON CORRECT ADMINISTRATION**

None

**10. WITHDRAWAL PERIOD**

Meat and offal : 14 days.

Milk: 6 days (144 hours).

**11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight of children.

Do not store above 25 °C

Protect from light

If accidentally frozen, shake vigorously before use.

Do not use after the expiry date stated on the label after “EXP”

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 insert, 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 WARNING(S)**

For topical application only.

All animals in a group should be treated.

To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer the product the end of the period of fly activity and before the larvae reach their resting sites: consult the veterinarian to know the correct treatment period.

Not to be mixed with other Veterinary Medicinal Products before administration.

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

The product can be toxic for fish and aquatic organisms.

Avoid spillage directly into water courses.

Any unused product or waste material should be disposed of in accordance with national requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

The product is packaged in 0.5, 1L, 2.5L and 5L HDPE containers.  
Not all pack sizes may be marketed.  
The product is safe for use in breeding animals.

For Animal Treatment Only.  
To be supplied only on veterinary prescription.