Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

MOXIGRO 5 mg/ml Pour-on Solution for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active Substances:	
Moxidectin	5.00 mg
Excipients:	
Butylated hydroxyanisole (E320)	0.10 mg
Tertiary Butylhydroquinone	0.03 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pour-on solution.
Pale yellow oily solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

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 eurysternus
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.

4.3 Contraindications

None known.
See Section 4.11.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 at 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

- 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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Moxidectin has been shown to be safe for use in pregnant and lactating animals and breeding bulls.
See Section 4.11.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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**.**

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No symptoms of overdose have been observed with the product given at ten times the recommended dose.
They are manifested as transient salivation, depression, drowsiness and ataxia. There is no specific antidote.

4.11 Withdrawal Period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QP54AB02
Therapeutic group: endectocide (milbemycin family)

5.1 Pharmacodynamic properties

Moxidectin is a parasiticide active against a wide range of important internal and external parasites. It is a second generation macrocyclic lactone of the milbemycin family. Its principal mode of action is interference with the GABA (gamma amino butyric acid) receptors involved with neuromuscular transmission.

Moxidectin stimulates the release of GABA and increases its binding to the postsynaptic receptors. The net effect is to open the chloride channels on the postsynaptic junction to allow the inflow of chloride ions and induce an irreversible resting state. This results in flaccid paralysis and eventual death of parasites exposed to the drug.

5.2 Pharmacokinetic properties

Following pour-on application, the drug is distributed throughout the body tissues (except muscle) but due to its lipophilicity the concentrations in fat are 5-15 times those in other tissues.
Moxidectin undergoes partial biotransformation by hydroxylation in the body and the only significant route of excretion is the faeces, where the parent compound accounts for approximately 50%.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated hydroxyanisole (E320)
Tertiary Butylhydroquinone
Aromatic Solvent
Myristal Propoxylate Propionic Ester
Polybutene Polymer
Propylene Glycol
Citric Acid Monohydrate (E330)
Fractionated coconut oil

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

Keep the container in the outer carton to protect from light.
Do not store above 25°C.
If accidentally frozen, shake vigorously before use.

6.5 Nature and composition of immediate packaging

0.5, 1, 2.5 and 5 litre fluorinated high-density polyethylene containers with polypropylene screw cap and polyethylene inner seal. Secondary pack: carton box containing 1 x 0.5 litre, 1 x 1 litre, 1 x 2.5 litre and 1 x 5 litre containers.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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.

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/119/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th May 2015

10 DATE OF REVISION OF THE TEXT