1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxodex 5 mg/ml Pour on solution for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Moxidectin 5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole E320	0.10 mg
Tert butyl hydroquinone E319	0.03 mg
Aromatic Solvent	-
Myristal Propoxylate Propionic Ester	-
Polybutene Polymer	-
Medium Chain Triglyceride	-
2-Tert-Buthylhydroquinone (E319)	
Butylhydroxyanisole (E320)	

A clear colourless to pale yellow solution.

3. CLINICAL PARTICULARS

3.1 Target species

Cattle.

3.2 Indications for use for each 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 viviparous

- 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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Not to be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

3.4 Special warnings

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 body weight, 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.
Partial cross-resistance between ivermectin and moxidectin has been reported in nematode parasites. Cases of resistance to moxidectin have been reported in gastrointestinal nematode parasites of cattle, in the EU and elsewhere. Therefore, use of this product should be based on local (regional, farm) epidemiological information about susceptibility of parasites, local history of treatments and recommendations on how to limit further selection for resistance to anthelmintics.

3.5 Special precautions for use

Special precautions for safe use in the target species:

For topical application only.
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:

- This product may be irritating to the skin and eyes.
- Avoid direct contact with skin and eyes.
- Personal protective equipment consisting of clothes and gloves should be worn when handling the veterinary medicinal product.
- Do not smoke, eat or drink while handling the product.
- If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.
- Wash hands after use.

Special precautions for the protection of 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 of 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.

4.6 Adverse reactions (frequency and seriousness)

Cattle

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction Neurological signs (including ataxia, trembling and lethargy)

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Fertility:

Can be used in breeding bulls.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Pour-on use.

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**.**

To ensure a correct dosage, body weight should be determined as accurately as possible.

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 overdosing.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal period

Meat and offal: 14 days.

Milk: 6 days (144 hours).

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AB02

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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%.

Environmental properties

Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance. In particular, in acute and chronic toxicity studies with algae, crustaceans and fish, moxidectin showed toxicity to these organisms, yielding the following endpoints:

Organism		**EC_{50}**	**NOEC**
Algae	*S. capricornutum*	>86.9 µg/l	86.9 µg/l
Crustaceans (Water fleas)	*Daphnia magna* (acute)	0.0302 µg/l	0.011 µg/l
	Daphnia magna (reproduction)	0.0031 µg/l	0.010 µg/l
Fish	*O. mykiss*	0.160 µg/l	Not determined
	L. macrochirus	0.620 µg/l	0.52 µg/l
	P. promelas (early life stages)	Not applicable	0.0032 µg/l
	Cyprinus carpio	0.11 µg/l	Not determined

EC_{50}: the concentration which results in 50% of the test species individuals being adversely affected, i.e. both mortality and sub-lethal effects.
NOEC: the concentration in the study at which no effects are observed.
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, all precautions for use and disposal must be adhered to.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 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.

5.3 Special precautions for storage

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

Shake vigorously before use.

Keep the container in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

1 L (Squeeze Pour), 2.5 L, 3 L (Same bottle as 2.5 L), 5 L and 6 L (3 L+3 L or 1 L +5 L) Fluorinated high density polyethylene (white) bottles with polypropylene tamper-evident cap (white or blue) with Alu seal

The 1 L squeeze-pour container includes an integrated dosing device with a measuring scale, graduated each 5 ml up to 25 ml.

Each pack size will be marketed with one container in a carton.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

The veterinary medicinal product should not enter water courses as moxidectin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited

7. MARKETING AUTHORISATION NUMBERS

VPA10987/129/001

8. DATE OF FIRST AUTHORISATION

24/01/2020

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

09/12/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).