PARTICULARS TO APPEAR ON THE OUTER PACKAGE {{Carton for 1L 2.5L 3L and 5L bottle}}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxodex 1 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance: Moxidectin 1.00 mg

3. PACKAGE SIZE

1L
2.5 L
3 L
5 L

4. TARGET SPECIES

Sheep

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period

Meat and offal: 14 days.

Milk: 5 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use by : …….
Once opened use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

14. MARKETING AUTHORISATION NUMBER

Vm 08749/4089

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {{Label for 1L 2.5L 3L and 5L bottle}}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxodex 1 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance: Moxidectin 1.00 mg

3. TARGET SPECIES

Sheep

4. ROUTES OF ADMINISTRATION

Oral use

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period
Meat and offal: 14 days.
Milk: 5 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by : …….
Once opened use within 6 months.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Moxodex 1 mg/ml oral solution for sheep

2. Composition

Each ml contains:
Active substance:
Moxidectin 1.00 mg
Excipient:
Benzyl Alcohol 40.0 mg
Clear colourless to yellowish solution

3. Target species

Sheep

4. Indications for use

For the treatment and prevention of mixed infections of sheep with parasites sensitive to moxidectin.

Adult and/or immature gastro-intestinal nematodes:

- *Haemonchus contortus* (including inhibited larvae)
- *Teladorsagia circumcincta* (including inhibited larvae)
- *Teladorsagia trifurcata*
- *Trichostrongylus axei* (including inhibited larvae)
- *Trichostrongylus colubriformis*
- *Trichostrongylus vitrinus*
- *Nematodirus battus*
- *Nematodirus spathiger*
- *Nematodirus filicolis* (adults only)
- *Strongyloides papillosus* (larval stages only)
- *Cooperia curticei* (adults only)
- *Cooperia oncophora*
- *Oesophagostomum columbianum*
- *Oesophagostomum venulosum* (adults only)
- *Chabertia ovina*
- *Trichuris ovis* (adults only)

Adult respiratory tract nematode:

- *Dictyocaulus filaria*

The product has a persistent effect in preventing reinfection:

for 5 weeks by *Teladorsagia circumcincta* and *Haemonchus contortus*

for 4 weeks by *Oesophagostomum columbianum*

Clinical trials, after experimental and natural infection, have shown that the product is effective against certain benzimidazole resistant strains of:

Haemonchus contortus

Teladorsagia circumcincta

Trichostrongylus colubriformis

Cooperia curticei

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

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.

Resistance to macrocyclic lactones has been reported in *Teladorsagia* in sheep in a number of countries. In 2018, throughout Europe, multiple resistance of *Teladorsagia circumcincta* to moxidectin, levamisole, benzimidazole and ivermectin were reported. Moxidectin resistant *Haemonchus contortus* and *Trichostrongylus colubriformis* were also described. Therefore the 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 use the product under sustainable conditions to limit further selection for resistance to antiparasitic compounds

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

- Avoid direct contact with skin and eyes.
- Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product.
- In the event of eye contact, flush the eye with copious amounts of clean water and seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands or any exposed area after use.
- Do not smoke or eat when handling this product.

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, 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 4 days 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 instructions in this leaflet. Based on the excretion profile of moxidectin when administered as the oral formulation to sheep, treated animals should not have access to watercourses during the first 3 days after treatment.

Pregnancy, lactation and fertility:

Moxidectin has been shown to be safe for use in pregnant, lactating and breeding animals. Can be used during pregnancy and lactation and in breeding animals.

Interaction with other medicinal products and other forms of interaction:

The effects of GABA(gamma amino butyric acid) agonists are increased by moxidectin.

Overdose:

Symptoms have not been observed at less than 5 times the recommended dose.

They are manifested as transient salivation, depression, drowsiness and ataxia 8 to 12 hours post-treatment. Treatment is not generally necessary, and recovery is generally complete within 24 to 48 hours. There is no specific antidote.

Major incompatibilities:

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

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.
Should be given as a single oral drench of 1 ml/5 kg live bodyweight, equivalent to 200 µg moxidectin/kg live bodyweight, using any standard drenching equipment.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing equipment should be checked.

10. Withdrawal periods

Meat and offal: 14 days.

Milk: 5 days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 applicable national collection systems. These measures should help to protect the environment.

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 08749/4089

Pack sizes are 1L, 2.5L, 3L and 5L

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea
Co Galway
Ireland
Tel: +353 (0)91 841788
E-mail: vetpharmacoviggroup@chanellegroup.ie

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

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.

POM-VPS

Approved 27 August 2025
Gavin Hall