1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Unomox 1 mg/ml oral solution for sheep.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Moxidectin 1.00 mg

Excipient:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl Alcohol	40.0 mg
Propylene Glycol	
Polysorbate 20	
Sodium Dihydrogen Phosphate Dihydrate	
Disodium Phosphate Dodecahydrate .	
Purified water	

Clear colourless to yellowish solution.

3. CLINICAL PARTICULARS

3.1 Target species

Sheep.

3.2 Indications for use for each target species

Infections of sheep with parasites sensitive to moxidectin.

For the treatment and prevention of infections caused by:

Adult and immature gastro-intestinal nematodes:

- *Haemonchus contortus* (including inhibited larvae)
- *Ostertagia circumcincta* (including inhibited larvae)
- *Ostertagia 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 oncoaphora*
- *Oesophagostomum columbianum*
- *Oesophagostomum venulosym* (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 *Ostertagia 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
Ostertagia circumcincta
Trichostrongylus colubriformis
Cooperia curticei

3.3 Contraindications

None.

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.

Resistance to macrocyclic lactones has been reported in *Teladorsagia* in sheep in a number of countries. In 2008, throughout Europe, moxidectin resistance is very rare; it has been reported in

a single case involving a levamisole-, benzimidazole and ivermectin-resistant strain of *Teladorsagia circumcincta*. 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. These precautions are especially important when moxidectin is being used to control resistant strains.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

- Avoid direct contact with skin and eyes.
- Wash hands after use.
- Do not smoke or eat when using this product.
- 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.

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 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 label instructions. 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.

3.6 Adverse events

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 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, lactation and fertility:

Moxidectin has been shown to be safe for use in pregnant, lactating and breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by moxidectin.

3.9 Administration routes and dosage

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.

To ensure administration of a correct dosage, body weight should be determined as accurately as possible; accuracy of the dosing should be checked. Do not mix with other products.

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

Symptoms generally do not occur 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.

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 periods

Meat and offal: 14 days.

Milk: 5 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

ATC Vet code: QP 54 AB 02

4.2 Pharmacodynamics

Moxidectin is a parasiticide active against a wide range of economically important internal and external parasites and is a second generation macrocyclic lactone of the milbemycin family. Its principal mode of action is interfering with neuromuscular transmission of the GABA (gamma amino butyric acid)-gated or glutamate-gated chloride channels. 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

Moxidectin is quickly absorbed after oral administration with peak plasma levels in less than 13 hours after dosing and is eliminated slowly with a t ½ life of approx. 7 days. The drug is distributed throughout the body tissues but due to its lipophilicity the target tissue is fat where concentrations are 10 to 20 times higher than those found in other tissues. Moxidectin undergoes limited biotransformation by hydroxylation. The only significant route of excretion is the faeces.

4.4 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: 24 months
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

White HDPE flexi containers containing 1L, 2.5 L, 3 L and 5 L of product. The containers are closed with polypropylene caps with tamper evident seals. Not all pack sizes may be marketed.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10987/119/001

8. DATE OF FIRST AUTHORISATION

25/8/2017

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

06/02/2024

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).