Summary of Product Characteristics

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:
Benzyl Alcohol 40.0 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution
Clear colourless to yellowish solution

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the 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

4.3 Contraindications

None

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
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.
- Wear impermeable rubber gloves during use.
- In the event of eye contact, flush the eye with copious amounts of clean water and seek medical advice.

Other precautions regarding impact on 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interactions

The effects of GABA agonists are increased by moxidectin.

4.9 Amounts to be administered and administration route

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.

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

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.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides (milbemycins)
ATC Vet code: QP 54 AB 02

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

5.3 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Propylene Glycol
Polysorbate 20
Disodium Phosphate Dodecahydrate
Sodium Dihydrogen Phosphate Dihydrate
Purified Water

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Do not contaminate watercourses with the product.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Ida Industrial Estate
Dublin Road
Loughrea
Co. Galway
Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/119/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 August 2017

10 DATE OF REVISION OF THE TEXT

February 2022