SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solantel 50 mg/ml Oral Suspension for Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:
Active substance:
Closantel 50.0 mg
(as Closantel Sodium Dihydrate 54.375 mg)

Excipient(s):
Propylene glycol (E1520) 217.6 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension
Off-white to yellow suspension.

4. CLINICAL PARTICULARS

4.1 Target Species

Sheep

4.2 Indications for use, specifying the target species

For the treatment of chronic and subacute fasciolosis (due to *Fasciola hepatica*). The product is effective against mature and late immature flukes (from 5 weeks immature).
For the treatment of *Oestrus ovis* (Sheep Nasal Bot Fly).
For the treatment of inhibited, L4 and adult stages of *Haemonchus contortus*.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.

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 closantel has been reported in *Haemonchus* species outside the EU. The use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

i. Special precautions for use in animals

When using a drenching gun, take care not to injure the mouth or pharynx.
Do not exceed the stated dose.

The product can be used in all age groups of sheep and lambs.

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

This product may be irritating to skin and eyes and users should be careful not to accidentally splash it on themselves or others.

Wear nitrile rubber gloves when applying the product.

In case of accidental spillage onto skin or into eyes, rinse the affected area with large amounts of clean water. If irritation persists, seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after use.

Do not eat, drink or smoke while handling the product.

iii. Other precautions

Closantel is very toxic to dung fauna.

The risk to dung fauna can be reduced by avoiding too frequent and repeated use of closantel (and products of the same anthelmintic class) in sheep and lambs. Animals should not normally be treated in excess of three times a year with closantel.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy. It can also be used in rams at any time including during the breeding season.
The safety of the veterinary medicinal product has not been established during lactation

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Give orally as a drench.

10 mg of closantel per kg bodyweight (i.e. 1 ml of product per 5 kg bodyweight).
For example:

Bodyweight	*Dose*
Up to 5 kg	1 ml
10 kg	2 ml
20 kg	4 ml
30 kg	6 ml
40 kg	8 ml
50 kg	10 ml
60 kg	12 ml
70 kg	14 ml
80 kg	16 ml

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. If animals are to be treated collectively rather than individually, they should be grouped according to their body weight and dosed accordingly in order to avoid under- or over-dosing.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of resistance developing.

Suitable for use with most types of standard drenching equipment.
Shake well before use.

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

Symptoms of acute overdosage are decreased vision or blindness, anorexia, in-coordination and general weakness.

4.11 Withdrawal period(s)

Meat and offal: 42 days

Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, phenol derivatives, including salicylanilides**.**
ATC Vet Code: QP52AG09

5.1 Pharmacodynamic properties

The product contains the salicylanilide closantel, a synthetic antiparasitic agent with high activity against liver fluke, haematophagous nematodes and the larval stages of some arthropods in sheep.

Closantel uncouples the mitochondrial oxidative phosphorylation resulting in inhibition of ATP synthesis. This induces a marked change in the energy metabolism of the parasite which finally kills it.

Closantel is active against benzimidazole resistant strains of *Haemonchus contortus*.

5.2 Pharmacokinetic particulars

Closantel is rapidly absorbed into the systemic circulation with peak plasma levels at 24-48 hours after dosing. The bioavailability of an oral dose is 50 %. In plasma, closantel is bound to albumin for more than 99 %. As a result, tissue distribution is very limited. On average, tissue levels are 15 times lower than plasma levels. The elimination half-life of closantel from plasma and tissues is approximately 2 to 4 weeks in sheep. Closantel is metabolised only to a slight extent and the main excretion route is the bile. The urinary excretion is negligible.

5.3 Environmental properties

Closantel has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of closantel may take place over a period of several weeks. Faeces containing closantel excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol (E1520)
Microcrystalline Cellulose and Carmellose Sodium
Hypromellose
Sodium Lauryl Sulfate
Simethicone Emulsion
Water purified

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: 2 years
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 30°C.
Keep the container in the outer carton in order to protect from light.
Store upright in the original container.
Protect from cold and shake well before use.

6.5 Nature and composition of immediate packaging

White high density polyethylene multidose container backpacks with high density polyethylene screw cap with induction-seal liners.

Pack sizes:
Box with 1 multidose container of 1 litre
Box with 1 multidose container of 2.5 litres
Box with 1 multidose container of 5 litres
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

Closantel may affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4402

9. DATE OF THE FIRST AUTHORISATION

04 August 2016

10. DATE OF REVISION OF THE TEXT

August 2021

Approved: 20/08/21