PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton for flexi pack containers- 6 litres (5 litres + 1 litre}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec 0.8mg/ml Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Ivermectin 0.8mg

3. PACKAGE SIZE

6 l (5 l +1 l)

4. TARGET SPECIES

Sheep

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat & Offal: 10 days.
Milk: Not authorised for use in lactating sheep producing milk for human consumption. Sheep must not be treated within 60 days prior to the commencement of lactation, if milk is to be used for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the container: 18 months.
Once opened, use by……..

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °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 Pharmaceutical Manufacturing Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 08749/4027

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {Label for 1 l, 2.5 l, 5 l, 6 l (5 l & 1 l) and 10 l }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animec 0.8mg/ml Oral Solution for Sheep

2. COMPOSITION

Each ml contains:

Active substance:
Ivermectin 0.8mg

Excipients:

Benzyl Alcohol (E1519)	28.6 mg
Butylhydroxyanisole (E320)	0.10 mg
Propyl Gallate (E310)	0.10 mg

A transparent, yellow coloured solution.

3. PACKAGE SIZE

1 l
2.5 l
5 l
6 l (5 l & 1 l)
10 l

4. TARGET SPECIES

Sheep

5. INDICATIONS FOR USE

Indications for use

For the treatment of infections with the following parasites:

Gastrointestinal roundworms (adult and fourth larval stage) -
Haemonchus contortus
Teladorsagia circumcincta
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.
Including *N. battus*
Strongyloides papillosus
Chabertia ovina

Lungworms (adult and fourth larval stage) - *Dictyocaulus filaria*

Nasal bot (all larval stages) - *Oestrus ovis*

6. CONTRAINDICATIONS

Contraindications

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

7. 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 or misadministration of the product.

Resistance to ivermectin (an avermectin) has been reported in *Teladorsagia* in sheep and goats within the EU and it is common in *Haemonchus* in sheep outside the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematode and recommendations on how to limit further selection for resistance to anthelmintics.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Fecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, and anthelmintic belonging to another pharmacological class and having different mode of action should be used.
The veterinary medicinal product has a cross-resistance with other avermectins and with milbemycins.

Special precautions for safe use in the target species:

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon.
Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing. Veterinary advice should also be sought if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance might be involved.

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

Wash hands after use.

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

Avoid contact with skin and eyes.

Personal protective equipment consisting of impervious gloves should be worn when handling the veterinary medicinal product.

As absorption through skin can occur, in the event of accidental skin contact, wash the affected area immediately with soap and water.

If accidental eye exposure occurs, flush the eyes immediately with water.

Special precautions for the protection of the environment:

The veterinary medicinal product is extremely dangerous to fish and aquatic life. Do not contaminate surface waters or ditches with the product or used container.

Other precautions:

Avermectins may not be well tolerated in non-target species. Cases of intolerance resulting in fatalities have been reported in dogs, especially Collies, Old English Sheep Dogs and related breeds or crosses, and also in turtles/tortoises.

Pregnancy and lactation:

Can be used during pregnancy and lactation provided that the milk is not used for human consumption.

Interactions with other medicinal products and other forms of interaction:

None known.

Overdose:

At doses up to 4 mg ivermectin per kg administered by stomach tube (20x the recommended dose level) undesirable toxic reactions occurred. Acute symptoms (ataxia, staggering gait, incoordination, depression) were observed at the dose rate of 8 mg/kg (40x the recommended dose level) during a study carried out on 4 animals. Twenty-four hours later, the animals showed only mild incoordination and depression.

Three days post dose, all the animals were nearly normal. It is possible that the signs of toxaemia were due to the propylene glycol.

No antidote has been identified. Symptomatic treatment may be beneficial.

Special restrictions for use and special conditions for use:

.Not applicable.

8. ADVERSE EVENTS

Adverse events

Sheep:

Frequency underdetermined:
Cough[1]

[1] immediately after treatment and this passing response is of no consequence.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, 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 using the contact details on this label, 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

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration
Oral use.

The recommended dose rate is 0.2 mg ivermectin per kg bodyweight (corresponding to 2.5 ml per 10 kg bodyweight).

The following table shows the actual dose to be given and the number of animals of differing bodyweights which can be dosed from this pack:

Weight Range (kg)	Dose Volume (ml)	Doses per 1 L Pack	Doses per 2.5 L Pack	Doses per 5 L Pack	Doses per 10 L Pack
Up to 10	2.5	400	1000	2000	4000
11-20	5.0	200	500	1000	2000
21-30	7.5	133	333	666	1333
31-40	10.0	100	250	500	1000
41-50	12.5	80	200	400	800
51-60	15.0	67	166	333	666

Over 60 kg give 2.5 ml per 10 kg bodyweight.

1 litre, treats 80 x 50 kg sheep and 200 x 20 kg lambs.
5 litres, treats 400 x 50 kg sheep and 1000 x 20 kg lambs.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

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

Accuracy of the dosing device should be checked. The use of suitably calibrated measuring equipment is recommended.

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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat & Offal: 10 days.
Milk: Not authorised for use in lactating sheep producing milk for human consumption. Sheep must not be treated within 60 days prior to the commencement of lactation, if milk is to be used for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30 °C

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

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

This veterinary medicinal product should not enter water courses as ivermectin is extremely 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 applicable national collection systems. These measures should help to protect the environment.

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

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 08749/4027

Pack sizes:
Flexi pack containers: 1 litre, 2.5 litres, 5 litres and 6 litres (5 litres +1 litre)
Jerry-cans containers: 1 litre, 2.5 litres, 5 litres and 10 litres

Not all pack sizes may be marketed.

16. 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.

17. CONTACT DETAILS

Contact details

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

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland
Tel: +353 (0)91 841788
E-mail: vetpharmacoviggroup@chanellegroup.ie

18. OTHER INFORMATION

Other information

POM-VPS

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the container: 18 months.

Once opened, use by…….

Shelf life after first opening the immediate packaging: 18 months.

21. BATCH NUMBER

Lot {number}

Gavin Hall

Approved: 27 August 2026