PARTICULARS TO APPEAR ON THE OUTER PACKAGE {50 ML CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 1% w/v solution for injection for sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Moxidectin 10 mg

3. PACKAGE SIZE

50 ml Treats 50 x 50 kg sheep

4. TARGET SPECIES

Sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 70 days.
Milk: Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

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

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

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5158

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {200 and 500 ML CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 1% w/v solution for injection for sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Moxidectin 10 mg

3. PACKAGE SIZE

200 ml	Treats 200 x 50 kg sheep
500 ml	Treats 500 x 50 kg sheep

4. TARGET SPECIES

Sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

Directions for use: 0.1 ml/5 kg bodyweight by subcutaneous injection (under the skin) in the neck. Use sterile 18 gauge needles or smaller, of half inch (1.5 cm) length. Determine sheep weight to ensure correct dose rate is used.

Routine Prevention of Scab: One injection at the recommended dosage will protect against *Psoroptes ovis* (scab mites) infestation for at least 28 days.

Treatment of Scab Outbreaks: Two injections at the recommended dosage, 10 days apart. The two injections must be given on different sides of the neck.

Bodyweight (kg)	Dose volume (ml)	Doses per pack (200 ml)	Doses per pack (500 ml)
20	0.4	500	1250
25	0.5	400	1000
30	0.6	333	833
40	0.8	250	625
50	1.0	200	500
60	1.2	166	416
70	1.4	142	357
80	1.6	125	312

EXAMPLE For sheep less than 20 kg bodyweight or over 80 kg bodyweight, give 0.1 ml per 5 kg bodyweight.

Prevention of scab

- For routine prevention, **all** sheep in the flock must be injected **once**.
- A single injection with the veterinary medicinal product will protect against sheep scab for at least 28 days from the time of treatment. If treated sheep come in contact with infested animals **after** that time, infestation can occur.
- All bought-in or returned animals should be treated and isolated for 12 days before mixing with the rest of the flock.
- Ensure adequate fencing between neighbouring flocks.

Treatment of Scab

- The signs of scab can be confused with those of the chewing louse *Bovicola (Damalinia) ovis*. As with other available endectocides the veterinary medicinal product is not effective against chewing lice. Consult your veterinary surgeon to ensure correct diagnosis.
- Inject **all** sheep in the affected flock or sub-flock, **twice**, 10 days apart.
- The two injections must be given on different sides of the neck.
- It is important to ensure that all in-contact sheep are treated.
- Sheep scab mites can remain infective off the animal, on fences, posts etc. for at least 16 days. Since the veterinary medicinal product protects for at least 28 days (i.e. longer than the time for which scab mites can survive off the animal) treated sheep can be immediately turned back onto the same pasture after dosing.
- Since the effect of any injectable on scab mites is not immediate, contact between treated infected sheep and non-treated, non-infected sub-flocks must be avoided until at least 12 days after the last treatment.

Treatment and Control of Worms

- For advice see package leaflet

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 70 days.
Milk: Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

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

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

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5158

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {50 ml, 200 ml and 500 ml BOTTLE LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin 1% w/v solution for injection for sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Moxidectin 10 mg

3. TARGET SPECIES

Sheep.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

Subcutaneous use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 70 days.
Milk: Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 6 months.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cydectin 1% w/v solution for injection for sheep

2. Composition

Each ml contains:

Active substance:

Moxidectin	10.0 mg

Excipients:

Benzyl Alcohol	40.0 mg
Butylated Hydroxytoluene	2.5 mg

A sterile, clear pale to yellow aqueous solution.

3. Target species

Sheep.

4. Indications for use

The veterinary medicinal product is an endectocide active against internal and external parasites in sheep. It contains moxidectin, a second-generation macrocyclic lactone of the milbemycin family.

Moxidectin is rapidly absorbed following subcutaneous injection (under the skin). It is distributed throughout the body tissues for a rapid effect on parasites and reaches highest concentrations in fat, from which it is slowly released back into the circulation. It is this “slow release” over a long period of time which is active against parasites picked up by sheep after dosing.

The veterinary medicinal product is effective against the following internal and external parasites of sheep.

Gastro-intestinal roundworms:
- *Haemonchus contortus*
- *Teladorsagia circumcincta* (including inhibited larvae)
- *Trichostrongylus axei* (adults)
- *Trichostrongylus colubriformis* (adults and L3)
- *Cooperia curticei* (adults)
- *Nematodirus spathiger* (adults)
- *Cooperia punctata* (adults)
- *Gaigeria pachyscelis* (L3)

• *Oesophagostomum columbianum* (L3)
• *Chabertia ovina* (adults)

Adult lungworm:
• *Dictyocaulus filaria*

Larvae of nasal bots:
• *Oestrus ovis* (L1, L2, L3)

Mange (scab) mites:
• *Psoroptes ovis*

PERSISTENT ACTIVITY
The veterinary medicinal product has a persistent effect in preventing infection or reinfection for:
• at least 4 weeks against *Psoroptes ovis* (scab mites)
• 5 weeks against *Teladorsagia circumcincta* and *Haemonchus contortus,*
• 4 weeks against *Gaigeria pachyscelis* and *Oesophagostomum columbianum,*
• 2 weeks against *Trichostrongylus colubriformis*.

Trials have shown that the veterinary medicinal product may be effective against strains of *Haemonchus contortus* resistant to benzimidazoles (white drenches), ivermectin and doramectin.

5. Contraindications

Do not use in animals that have any history of previous vaccination against footrot.

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 bodyweight, 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

moxidectin should be based on local (regional, farm) epidemiological information about susceptibility of nematodes, local history of treatments and recommendations on how to use the product under sustainable conditions to limit further selection for resistance to anthelmintics. These precautions are especially important when moxidectin is being used to control resistant strains.

Special precautions for safe use in the target species:
It is important to treat at the recommended dosage and to avoid underdosing since this will result in spread of sheep scab.

Signs of sheep scab can be confused with chewing louse infestation, against which the product is not effective.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of contact with skin and eyes wash affected area with clean water.
Do not smoke, eat or drink while handling the product.
Wash hands after use.

To the physician: In cases of accidental self-injection treat any specific signs symptomatically.

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 more than 4 weeks 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 injectable

formulation to sheep, treated animals should not have access to watercourses during the first 11 days after treatment.

Pregnancy:
Can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction:
There are no known interactions with other animal health products used routinely in sheep such as mineral supplements, fluke, or worm treatments, or clostridial vaccines.

Overdose:
The symptoms of overdose are consistent with mode of action of moxidectin and generally do not occur at less than 10 times the recommended dose. They are manifested as transient salivation, depression, drowsiness, and ataxia 8 and 12 hours post-treatment. No treatment is generally necessary. The symptoms resolve in 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 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

Subcutaneous use.

Dose rate: 0.1 ml per 5 kg bodyweight (based on a recommended dose rate of 0.2 mg moxidectin per kg bodyweight) administered by subcutaneous injection in the neck.

Use the following table as a guide:

Bodyweight (kg)	Dose volume (ml)	Single Doses per Pack		
		50 ml	**200 ml**	**500 ml**
20	0.4	125	500	1,250
25	0.5	100	400	1,000
30	0.6	83	333	833
40	0.8	62	250	625
50	1.0	50	200	500
60	1.2	41	166	416
70	1.4	35	142	357
80	1.6	31	125	312

For sheep less than 20 kg bodyweight or over 80 kg bodyweight, dose at 0.1 ml per 5 kg.

9. Advice on correct administration

Use sterile 18-gauge needles or smaller, of half inch (1.5 cm) length.

Ensure that the needle is inserted carefully under the skin using aseptic precautions and that the product does not leak from the injection site. Be certain that the needle has penetrated the skin before delivering the dose.

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 bodyweight and dosed accordingly, in order to avoid under or overdosing. As with any scab treatment, underdosing can cause suppression and spread of the disease.

When treating groups of animals, use only the CYDECTIN® Automatic Injector and vented draw-off system. For the treatment of individual sheep, a syringe not exceeding 2.5 ml and calibrated in increments of 0.1 ml should be used. Syringes must be filled from the vial through a dry, sterile draw-off needle that has been placed in the vial stopper. Vial stoppers must not be broached more than 10 times.

Prevention and Treatment of Scab

Prevention of scab
• For routine prevention, **all** sheep in the flock must be injected once.
• A single injection with the veterinary medicinal product will protect against sheep scab for at least 28 days from the time of treatment. If treated sheep come in contact with infected animals **after** that time, infestation can occur.
• All bought-in or returned animals should be treated and isolated for 12 days before mixing with the rest of the flock.
• Ensure adequate fencing between neighbouring flocks.

Treatment of Scab Outbreaks
• The signs of scab can be confused with those of the chewing louse *Bovicola* (*Damalinia*) *ovis*. As with other available endectocides the veterinary medicinal product is not effective against chewing lice. Consult your veterinary surgeon to ensure correct diagnosis.
• Inject **all** sheep in the affected flock or sub-flock, **twice**, 10 days apart.
• The two injections must be given on different sides of the neck.
• It is important to ensure that all in-contact sheep are treated.
• Sheep scab mites can remain infective off the animal, on fences, posts etc. for at least 16 days. Since the veterinary medicinal product protects for at least 28 days (i.e. longer than the time for which scab mites can survive off the animal) treated sheep can be immediately turned back onto the same pasture after dosing.
• Since the effect of any injection on scab mites is not immediate, contact between treated infected sheep and non-treated, non-infected sub-flocks must be avoided until at least 12 days after the last treatment.

Treatment and Control of Worms

Dosing guidelines
The veterinary medicinal product is a member of the avermectin/milbemycin 3-ML class of anthelmintics. The advice of a veterinary surgeon should be sought in using the veterinary medicinal product in a dosing programme, to ensure correct diagnosis of the nematode infection present and to minimise the risk of developing resistance.

10. Withdrawal periods

Meat and offal: 70 days.
Milk: Not authorised for use in animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. 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.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste material 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5158

Pack sizes:
50, 200, and 500 ml.

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 contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

17. Other information

POM-VPS

Gavin Hall

Approved: 14 January 2026