PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxidectin EU Pharmaceuticals 5 mg/ml Pour-on solution for cattle.

Moxidectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Moxidectin 5 mg/ml

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

1 L

2.5 L

3 L

5 L

2 x 3 litres

5 litres + 1 litre

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For the treatment of infections of cattle with parasites sensitive to moxidectin.

Please read the leaflet for the full list of parasites.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

500 µg moxidectin/kg body weight (1 ml for 10 kg) as a single topical application.

Body weight (kg)	Dose Volume (ml) per animal	Doses per 1L Pack	Doses per 2.5L Pack	Doses per 3L Pack	Doses per 5L Pack	Doses per 6L Pack
200	20	50	125	150	250	300
300	30	33	83	100	166	200
400	40	25	62	75	125	150
500	50	20	50	60	100	120
600	60	16	41	50	83	100

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days.

Milk: 6 days (144 hours).

9. SPECIAL WARNING(S), IF NECESSARY

Environmental risks have been identified for this product and special precautions apply.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from frost.

Shake vigorously before use.

Store the container in an upright position.

Keep the container in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

Loughrea

Co. Galway

H62 FH90

Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/3113

17. MANUFACTURER'S BATCH NUMBER

BN{number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxidectin EU Pharmaceuticals 5 mg/ml Pour-on solution for cattle.

Moxidectin

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Moxidectin 5 mg/ml

3. PHARMACEUTICAL FORM

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5. TARGET SPECIES

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300	30	33	83	100	166	200
400	40	25	62	75	125	150
500	50	20	50	60	100	120
600	60	16	41	50	83	100

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days.

Milk: 6 days (144 hours).

9. SPECIAL WARNING(S), IF NECESSARY

Environmental risks have been identified for this product and special precautions apply.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened, use by : …….

Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from frost.

Shake vigorously before use.

Store the container in an upright position.

Keep the container in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

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Chanelle Pharmaceuticals Manufacturing Ltd

Loughrea

Co. Galway

H62 FH90

Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/3113

17. MANUFACTURER'S BATCH NUMBER

BN{number}

PACKAGE LEAFLET FOR:

Moxidectin EU Pharmaceuticals 5 mg/ml Pour-on Solution for Cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
H62 FH90
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxidectin EU Pharmaceuticals 5 mg/ml Pour-on Solution for Cattle.
Moxidectin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml of clear, colourless to pale yellow solution contains:
Active substance:
Moxidectin 5 mg

Excipients:

Butylhydroxyanisole E320	0.10 mg
Tert butyl hydroquinone	0.03 mg

4. INDICATIONS

Infections of cattle with parasites sensitive to moxidectin.
For the treatment of infections caused by:

- Adult and larval gastro-intestinal nematodes:

Haemonchus placei

Ostertagia ostertagi (including inhibited larvae)

Trichostrongylus axei

Nematodirus helvetianus

Cooperia oncophora

Cooperia punctata (adults)

Oesophagostomum radiatum (adults)

Bunostomum phlebotomum (adults)

- Adult respiratory tract nematode

Dictyocaulus viviparous

- Warbles (migrating larvae)

Hypoderma bovis

Hypoderma lineatum

- Lice

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

Bovicola bovis (Damalinia bovis)

- Mange Mites

Sarcoptes scabiei

Psoroptes ovis

Chorioptes bovis

- **Horn Flies**

Haematobia irritans

The product has a persistent effect in preventing against reinfection by:
Ostertagia ostertagi for 5 weeks
Dictyocaulus viviparus for 6 weeks.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Not to be used in other species as severe adverse reactions, including fatalities in dogs, may occur.

6. ADVERSE REACTIONS

Reactions at the site of application may occur after application in very rare occasions.
Neurological signs (including ataxia, trembling and lethargy) have been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

500 µg moxidectin/kg body weight (1 ml for 10 kg) as a single topical application.
To be administered along the midline of the back of the animal from the withers to the tailhead.
Apply to clean healthy skin**.**

Body weight (kg)	Dose Volume (ml) per animal	Doses per 1L Pack	Doses per 2.5L Pack	Doses per 3L Pack	Doses per 5L Pack	Doses per 6L Pack
200	20	50	125	150	250	300
300	30	33	83	100	166	200
400	40	25	62	75	125	150
500	50	20	50	60	100	120
600	60	16	41	50	83	100

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible.
For the treatment of a group of animals of the same or of a similar age, the dosing should be done according to the heaviest animal of this group.

10. WITHDRAWAL PERIOD

Meat and offal: 14 days.
Milk: 6 days (144 hours).

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from frost. Shake vigorously before use.
Keep out of the sight and reach of children.
Keep the container in the outer carton in order to protect from light.
Store the container in an upright position.
Shelf life after first opening the immediate packaging: 6 months.

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

12. SPECIAL WARNING(S)

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 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. Selection of resistant genes leading to the development of resistance can ultimately result in ineffective anthelmintic therapy.

Partial cross-resistance between ivermectin and moxidectin has been reported in nematode parasites. Cases of resistance to moxidectin have been reported in gastrointestinal nematode parasites of cattle. Therefore, 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 limit further selection for resistance to anthelmintics.

Special precautions for use in animals:

For topical application only.

Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

Care should be taken to avoid ingestion of spilled product or access to containers by these other species.

To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or the spine, it is recommended to administer the product at the end of the period of fly activity and before the larvae reach their resting sites: consult the veterinarian to know the correct treatment period.
Disease associated with warble fly is notifiable in some regions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product can cause skin and eye irritation. Avoid direct contact with skin and eyes. Do not smoke, eat or drink when handling this product.
Wear impermeable rubber gloves and protective clothing during use.
Wash hands or any exposed area after use.
In the event of eye contact, flush the eye with copious amounts of clean water and seek medical advice.

Use during pregnancy and lactation:
Moxidectin has been shown to be safe for use in pregnant and lactating animals and breeding bulls.

Interaction with other medicinal products and other forms of interaction:
None known

Overdose (symptoms, emergency procedures, antidotes):
No symptoms of overdose have been observed with the product given at ten times the recommended dose. They are manifested as transient salivation, depression, drowsiness and ataxia. There is no specific antidote.

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

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, 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 cattle with the product, levels of moxidectin that are potentially toxic to dung fly species may be excreted over a period of more than 2 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, field studies 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. 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, the product should be used only according to the label instructions. Based on the excretion profile of moxidectin when administered as the pour-on formulation, **treated animals should not have access to watercourses during the first week after treatment.**

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. 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.

15. OTHER INFORMATION

Pack size: 1L, 2.5L 3L and 5L

Multi pack of 2 x 3 litres and 5 litres + 1 litre

Not all pack sizes may be marketed.

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Gavin Hall
Approved: 17 October 2025