A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton for 1L 2.5L 3L and 5L bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxidectin (EU Pharmaceuticals) 1 mg/ml oral solution for sheep.

Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 1.00 mg of Moxidectin

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

1L

2.5 L

3 L

5 L

5. TARGET SPECIES

Sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 14 days.

Milk: 5 days.

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 : …….

Shelf-life after first opening the immediate packaging: 6 months.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

16. MARKETING AUTHORISATION NUMBER(S)

Vm 39787/4095

17. MANUFACTURER'S BATCH NUMBER

BN{number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 1 L, 2.5 L, 3L AND 5 L}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxidectin (EU Pharmaceuticals) 1 mg/ml oral solution for sheep.

Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 1.00 mg of Moxidectin

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

1 L

2.5 L

3 L

5 L

5. TARGET SPECIES

Sheep

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

For oral use.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 14 days.

Milk: 5 days.

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 _____

Shelf life after first opening the immediate packaging: 6 months.

11. SPECIAL STORAGE CONDITIONS

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

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

Read the package leaflet before use.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

16. MARKETING AUTHORISATION NUMBER(S)

Vm 39787/4095

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Moxidectin (EU Pharmaceuticals) **1 mg/ml oral solution for sheep.**

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

Marketing authorisation holder:
EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

Manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway, Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxidectin (EU Pharmaceuticals) 1 mg/ml oral solution for sheep.
Moxidectin

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

Clear colourless to yellowish solution
One ml contains:

Active substance:

Moxidectin	1.00 mg

Preservative:

Benzyl Alcohol	40 mg

4. INDICATION(S)

For the treatment and prevention of infections caused by the following worm species, susceptible to moxidectin:
Adult and immature gastro-intestinal nematodes:

- *Haemonchus contortus* (including inhibited larvae)
- *Ostertagia circumcincta* (including inhibited larvae)
- *Teladorsagia 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 oncophora*
- *Oesophagostomum columbianum*
- *Oesophagostomum venulosum* (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 *Teladorsagia 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

Teladorsagia circumcincta

Trichostrongylus colubriformis

Cooperia curticei

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None known.

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

7. TARGET SPECIES

Sheep.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dosage, body weight should be determined as accurately as possible; the accuracy of the dosing device should be checked. Do not mix with other products.

10. WITHDRAWAL PERIOD

Meat and offal: 14 days.

Milk: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

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

Keep out of the sight and reach of children.

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.

Shelf life after first opening the immediate packaging: 6 months.

When the container is broached (opened) for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf-life of the product is given on this package insert. This discard date should be written on the space provided on the label.

12. SPECIAL WARNING(S)

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 2019, throughout Europe, moxidectin resistance is very rare; it has been reported in a case involving a levamisole-, benzimidazole- and ivermectin-resistant strain of *Teladorsagia circumcincta* and a case involving an ivermectin-resistant strain of *T. 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.

User precautions

This product can cause skin and eye irritation.
Avoid direct contact with skin and eyes.
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.
Wash hands or any exposed area after use.
Do not smoke, eat or drink when handling this product.

Pregnancy and lactation

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

Incompatibilities

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

Interaction with other medicinal products and other forms of interaction

The effects of GABA agonists are increased by moxidectin.

Overdose (symptoms, emergency procedures, antidotes)

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.

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 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.

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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

15. OTHER INFORMATION

Pack sizes are 1L, 2.5L, 3L and 5L

Not all pack sizes may be marketed.

Approved 29 April 2022