PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovimox LA 100 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Moxidectin	100 mg

3. PACKAGE SIZE

50 ml.
250 ml.

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous injection.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 108 days.
Milk: Not permitted for use in lactating animals producing milk for human consumption or industrial purposes or within 80 days of expected parturition.
The withdrawal period is based solely on a single injection at the ear site of injection.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the container: 28 days.
Once broached/opened, use by: …

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

14. MARKETING AUTHORISATION NUMBERS

Vm 08749/5199

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovimox LA 100 mg/ml Solution for Injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Moxidectin 100 mg

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Subcutaneous injection.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 108 days.
Milk: Not permitted for use in lactating animals producing milk for human consumption or industrial purposes or within 80 days of expected parturition.
The withdrawal period is based solely on a single injection at the ear site of injection.

6. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the container: 28 days.
Once broached/opened use by:…

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

Chanelle Pharmaceuticals Manufacturing Ltd

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LABEL 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovimox

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Moxidectin 100 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the container: 28 days.
Once broached/opened, use by: …

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bovimox LA 100 mg/ml Solution for Injection for Cattle.

2. Composition

Each ml contains:

Active substance
Moxidectin 100 mg

Excipients
Benzyl Alcohol (E1519) 70 mg
Butylhydroxytoluene 0.6 mg

Clear, yellow liquid, free of visible particles.

3. Target species

Cattle.

4. Indications for use

In cattle weighing from 100 to 500 kg body weight, treatment and prevention of mixed infestations by the following gastro-intestinal nematodes, respiratory nematodes and certain arthropod parasites:

Adult and immature gastro-intestinal nematodes:
. *Haemonchus placei*
. *Haemonchus contortus*
. *Ostertagia ostertagi* (including inhibited larvae)
. *Trichostrongylus axei*
. *Trichostrongylus colubriformis*
. *Nematodirus helvetianus* (adults only)
. *Nematodirus spathiger*
. *Cooperia surnabada*
. *Cooperia oncophora*
. *Cooperia pectinata*
. *Cooperia punctata*
. *Oesophagostomum radiatum*
. *Bunostomum phlebotomum* (adults only)
. *Chabertia ovina* (adults only)
. *Trichuris spp.* (adults only)

Adult and immature respiratory tract nematode
. Dictyocaulus viviparus

Warble grubs (migrating larvae)
. Hypoderma bovis
. Hypoderma lineatum

Lice
. Linognathus vituli
. Haematopinus eurysternus
. Solenopotes capillatus
. Bovicola bovis (aid in control)

Mange mites
. Sarcoptes scabiei
. Psoroptes ovis
. Chorioptes bovis (aid in control)

The veterinary medicinal product has a persistent action and protects cattle for a certain duration against infection or re-infection with the following parasites for the period indicated:

Species	**Protection period (days)**
Dictyocaulus viviparous	120
Ostertagia ostertagi	120
Haemonchus placei	90
Oesophagostomum radiatum	150
Trichostrongylus axei	90
Linognathus vituli	133

The veterinary medicinal product is effective against *Hypoderma* larvae at the time of treatment but its persistent activity against *Hypoderma* has not been evaluated. If the product is given before the end of the fly season complimentary treatment with a product effective against *Hypoderma* may be required.

Persistent efficacy periods have not been established for parasite species other than those included in the above list. Therefore, re-infection of animals on pasture contaminated by parasites other than these remains possible before the end of the 90 day minimum persistency period demonstrated for specific species.

5. Contraindications

Do not use in animals less than 100 kg bodyweight or greater than 500 kg.
Do not inject the product by intravascular route. Intravascular injection may result in ataxia, paralysis, convulsions, collapse and death. To prevent any intravascular injection, carefully follow the administration procedure described in item “Dosage for each species, routes and method of administration.”
Do not use in cases of hypersensitivity to the active substance or any of the excipients.

6. Special warnings

Special warnings:
Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal and/or herd.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd should be sought from the responsible veterinarian.

Underdosing may result in ineffective use and may favour resistance development; therefore, underestimation of bodyweight and misadministration of the product must be avoided (see section 3.9. Administration routes and dosage).

The use of this product should take into account local information about susceptibility of the target parasites, where available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authority.

Where the results of tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

In the absence of risk of co-infection, a narrow spectrum product should be used.

Special precautions for safe use in the target species:
In order to prevent abscesses, a strict aseptic technique is recommended. The product has been formulated specifically for subcutaneous injection in dorsal surface of the ear of cattle and must not be given by any other route of administration or to any other species.

To avoid possible secondary reactions by the death of *Hypoderma* larvae in the spine or the oesophagus of animals, it is recommended to administer a product effective against *Hypoderma* larvae after the end of fly activity and before the larvae reach their resting sites. Consult your veterinary surgeon on the correct timing of this treatment.

Immunity to nematodes depends on adequate exposure to infection. Although not normally the case, circumstances could occur in which anthelmintic control measures

might increase the vulnerability of cattle to re-infection. Animals may be at risk towards the end of their first grazing season, particularly if the season is long, or in the following year if they move onto heavily contaminated pasture. In such instances, further control measures may be necessary.

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, drink, or eat while handling the product.
Wash hands after use.
If accidental skin contact occurs, wash the affected area with soap and water.
If accidental eye exposure occurs, immediately rinse the eyes thoroughly with water
If skin or eye irritation persists, seek medical attention.
Take care to avoid self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Advice to medical practitioners: In case of accidental self-injection: Treat 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:

- 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 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, 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. The product should be used only according to the label instructions. Based on the excretion profile of moxidectin when administered as the injectable formulation, treated animals should not have access to watercourses during the 10 days after treatment.

Pregnancy and lactation:
Can be used during pregnancy. However, note section 5 Contraindications and section 10 Withdrawal Periods.

Interaction with other medicinal products and other forms of interaction:
The effects of GABA agonists are increased by moxidectin.

Overdose:
Reactions at the injection site have to be expected more frequently and severe depending on the injected volume. Systemic signs of overdoses are consistent with the mode of action of moxidectin. These signs are manifested as transient salivation, depression, drowsiness and ataxia 24 to 36 hours post-treatment. The systemic signs usually disappear within 36 to 72 hours without treatment. At doses >3 times the recommended dose divided on both ears, the systemic signs included recumbency, muscle tremor, ruminal tympany and dehydration, which were resolved after treatment with fluids. The systemic signs can last for a few days to ten days. 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

Cattle

Rare (1 to 10 animals / 10,000 animals treated):	Injection site swelling[1,2] Depression and ataxia
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site abscess[2]

[1]immediate or delayed, may further develop into injection site abscesses, frequency tends to be higher in heavier animals.

[2]generally disappear without treatment within 14 days after administration, although may persist up to 5 weeks (<5% of cases) or longer (very rare occasions). In case of hypersensitivity reactions, a symptomatic treatment should be applied.

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

Dosage is 0.5 ml/50 kg bodyweight, equivalent to 1.0 mg moxidectin/kg bodyweight, given by a single subcutaneous injection in the ear using an 18 gauge, 25 – 40 mm hypodermic needle. The 50 ml vial stoppers must not be broached more than 20 times. Use automatic syringe equipment for the 250 ml vial, no more than five piercings should be made.

Underdosing could result in ineffective use and may favour resistance development. To ensure that the correct dosage is used, an animal's bodyweight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals in a group should be dosed at a rate corresponding to the heaviest one.
Accuracy of the dosing device should be thoroughly checked.

The injection should be given subcutaneously in the loose tissues on the dorsal surface of the ear, just distal to the distal edge of the auricular cartilage.

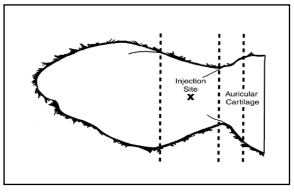
The dorsal (outer) surface of the ear should first be cleansed with antiseptic and allowed to briefly air dry. Palpate the edge of the auricular cartilage closest to the head, on the dorsal (hairy) surface of the ear. From this landmark, taking care to avoid blood vessels (artery, vein), the needle should be inserted subcutaneously starting at a point approximately 3 to 3.5 cm distal to this edge (away from the head), and directed towards the base of the ear, and the needle advanced to the hub. At this point, gently aspirate the syringe to confirm that the needle is not in a blood vessel.

Upon injection, the resulting depot should reside just distal to the edge of the auricular cartilage.

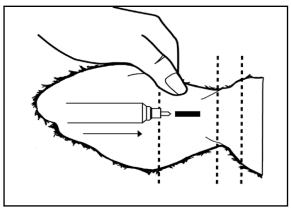
Following administration, the needle is withdrawn from the skin as pressure is applied for several seconds with the thumb at the point of insertion.

Due to the long-lasting protection against *Dictyocaulus viviparus* and the stomach worms, *Ostertagia ostertagi* and *Haemonchus placei*, a single treatment with the formulation at turn-out helps control parasitic bronchitis (lungworm) and parasitic gastro-enteritis throughout the grazing season by reducing the build-up of infective larvae on pasture associated with these parasites. For best results, the injection should be given to each calf of target weight to be grazed together immediately prior to being turned out to pasture. Animals should be set stocked throughout the grazing season or moved to a pasture which has not been grazed by other cattle earlier in the season.

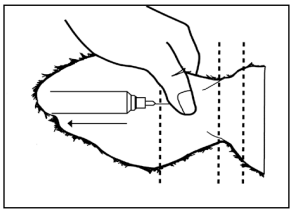
Diagram: Ear injection procedure



- The injection site is approximately 3.5 cm (1.5 inches) distal to the distal edge of the auricular cartilage.



- Use one hand to grasp and steady the ear.
- Inject subcutaneously using an 18 gauge x 1 inch needle.



- Inject contents. Depot should be just distal to the distal edge of the auricular cartilage.
- Apply pressure at the point of insertion as the needle is withdrawn from the skin to help seal the opening.

9. Advice on correct administration

To avoid possible anaphylactic type reaction, avoid intravenous administration.

10. Withdrawal periods

Meat and offal: 108 days.
Milk: Not permitted for use in lactating animals producing milk for human consumption or industrial purposes or within 80 days of expected parturition.

The withdrawal period is based solely on a single injection at the ear site of injection.

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 after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

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 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08749/5199

50 ml
250 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 manufacturer responsible for batch release:
Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
H62 FH90
Ireland

Contact details to report suspected adverse reactions:
EU Pharmaceuticals Ltd
37 Geraldine Road
London
SW18 2NR

17. Other information

POM-VPS

Gavin Hall
Approved: 03 November 2025