

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton – HDPE bottle - 50 ml & 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxisolv LA 100 mg/ml Solution for Injection for Cattle
Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Moxidectin 100 mg

Excipient:

Benzyl Alcohol (E1519) 70 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

200 ml

5. TARGET SPECIES

Cattle

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 108 days.

Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 80 days of expected parturition.

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

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 within 28 days:

Once opened, use by: _____.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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

Bimeda Animal Health Limited
2 / 3 / 4 Airtown Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)
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Vm 50146/5001

17. MANUFACTURER'S BATCH NUMBER
--

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label – HDPE bottle - 50 ml & 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxisolv LA 100 mg/ml Solution for Injection for Cattle
Moxidectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Moxidectin 100 mg

Excipient:

Benzyl Alcohol (E1519) 70 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml

200 ml

5. TARGET SPECIES

Cattle

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 108 days.

Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 80 days of expected parturition.

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

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 within 28 days.
Once opened use by: _____

11. SPECIAL STORAGE CONDITIONS

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

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

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)
--

Vm 50146/5001

17. MANUFACTURER'S BATCH NUMBER
--

Lot

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Moxisolv LA 100 mg/ml Solution for Injection for Cattle

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

Marketing authorisation holder and manufacturer responsible for batch release:

Bimeda Animal Health Limited
2 / 3 / 4 Airtown Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Moxisolv LA 100 mg/ml Solution for Injection for Cattle
Moxidectin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:

Moxidectin 100 mg

Excipients:

Benzyl Alcohol (E1519) 70 mg

Clear yellow solution free for any particulate matter.

4. INDICATIONS

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 (reduction of infestation)

Mange mites:
Sarcoptes scabiei
Psoroptes ovis
Chorioptes bovis (reduction of infestation)

Moxidectin 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):
<i>Dictyocaulus viviparus</i>	120
<i>Ostertagia ostertagi</i>	120
<i>Haemonchus placei</i>	90
<i>Oesophagostomum radiatum</i>	150
<i>Trichostrongylus axei</i>	90
<i>Linognathus vituli</i>	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 veterinary medicinal 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 veterinary medicinal 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, route and method of administration".

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

6. ADVERSE REACTIONS

Immediate or delayed swelling can be observed at the injection site on rare occasions. These swellings may further develop into abscesses (approx. 1% of cases). The frequency of injection site swellings tends to be higher in the heavier animals. These side effects generally disappear without treatment, within 14 days after administration, some may persist for up to 5 weeks in a number of animals (<5%) and in very rare occasions longer.

Depression and ataxia can be observed on rare occasions after injection. In case of hypersensitivity reactions, a symptomatic treatment should be applied.

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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively, you can report via your national reporting system.

7. TARGET SPECIES

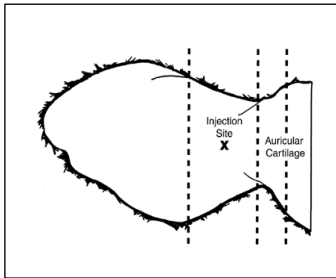
Cattle

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

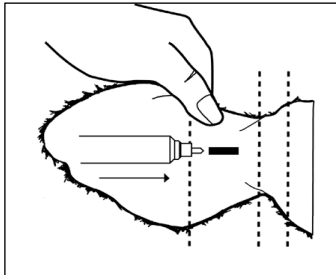
Subcutaneous use.

Dosage is 1.0 mg moxidectin per kg bodyweight (equivalent to 0.5 ml of the veterinary medicinal product per 50 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 30 times, and the 200 ml vial stoppers must not be punctured more than 50 times. Use automatic syringe equipment for the 200 ml fill size.

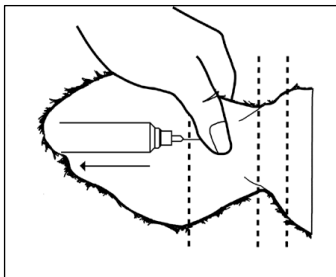
Diagram: Ear injection procedure



- 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

Shake well before use.

Underdosing could result in ineffective use and may favour resistance development. To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogenous groups should be set up, and all animals of a group should be dosed at the 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.

10. WITHDRAWAL PERIODS

Meat and offal: 108 days.

Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption 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.

This veterinary medicinal product does not require any special storage conditions. 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 WARNINGS

Special warnings for each target species:

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 herd.

Repeated use for an extended period, particularly when using the same class of substance, 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.

Partial cross-resistance between ivermectin and moxidectin has been reported in nematode parasites. Cases of resistance to moxidectin have been reported in *Cooperia*, *Ostertagia*, *Oesophagostomum* and *Trichuris* genera of gastrointestinal nematode parasites of cattle and in *Psoroptes* mites, in the EU and elsewhere.

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 (FECRT)).

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authority.

Special precautions for use in animals:

In order to prevent abscesses, a strict aseptic technique is recommended. The veterinary medicinal 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:

Moxidectin or benzyl alcohol may cause hypersensitivity (allergic reactions). People with known hypersensitivity to moxidectin or benzyl alcohol should avoid contact with the product.

The product may cause skin and eye irritation. Avoid direct contact with skin and eyes. If skin or eye irritation occur, wash with plenty of water.

Wash hands after use.

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

Take care to avoid self-injection. In case of accidental self-injection, seek medical advice.

Advice to medical practitioners in case of accidental self-injection: Treat symptomatically.

Pregnancy, lactation or lay:

Can be used during pregnancy. However, note 5. Contraindications, and 10 Withdrawal periods.

Interaction with other medicinal products and other forms of interaction:

The effects of GABA agonists are increased by moxidectin.

Overdose (symptoms, emergency procedures, antidotes):

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

dehydration, which were resolved after treatment with fluids. The systemic clinical signs can last for a few days to ten days. 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 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. 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 injectable formulation, treated animals should not have access to watercourses during the first 10 days after treatment.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, 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

March 2023

15. OTHER INFORMATION

Package sizes:

Carton box with 1 bottle containing 50 ml of product.

Carton box with 1 bottle containing 200 ml of product.

Not all pack sizes may be marketed.

Approved 31 March 2023

