SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

MoxiSolv 18.92 mg/g Oral Gel for Horses and Ponies

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

ACTIVE SUBSTANCE:

Moxidectin 18.92 mg

EXCIPIENTS:

Benzyl Alcohol (E1519) 37.84 mg
Butylhydroxytoluene 0.114 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral gel.
Pale yellow to yellow, clear gel.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 INDICATIONS FOR USE, SPECIFYING THE TARGET SPECIES

Horses (including ponies): for treatment of infections caused by moxidectin sensitive strains of:

- Large strongyles:
× *Strongylus vulgaris* (adults and arterial stages)
× *Strongylus edentatus* (adults and visceral stages)
× *Triodontophorus brevicauda* (adults)

× *Triodontophorus serratus* (adults)
× *Triodontophorus tenuicollis* (adults)

- Small strongyles (adults and intraluminal larval stages):
× *Cyathostomum* spp.
× *Cylicocyclus* spp.
× *Cylicostephanus* spp.
× *Cylicodontophorus* spp.
× *Gyalocephalus* spp.

- Ascarids:
× *Parascaris equorum* (adult and larval stages)

- Other species:
× *Oxyuris equi* (adult and larval stages)
× *Habronema muscae* (adults)
× *Gasterophilus intestinalis* (L2, L3)
× *Gasterophilus nasalis* (L2, L3)
× *Strongyloides westeri* (adults)
× *Trichostrongylus axei*

The veterinary medicinal product has a persistent efficacy of two weeks against small strongyles. The excretion of small strongyles eggs is suppressed for 90 days.

The veterinary medicinal product is effective against (developing) intramucosal L4 stages of small strongyles. At 8 weeks after treatment, early (hypobiotic) L3 stages of small strongyles are eliminated.

4.3 CONTRAINDICATIONS

Do not administer to young foals less than 4 months.
Do not use in cases of hypersensitivity to the active substance, to any other milbemycins or to any of the excipients.

4.4 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 individual animal.
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.

Partial cross-resistance between ivermectin and moxidectin has been reported. Cases of resistance to moxidectin have been reported in equine cyathostomins, *Parascaris equorum, Oxyuris equi* 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. the Faecal Egg Count Reduction Test (FECRT)).
A shorter egg re-appearance periods after treatment with moxidectin is an early indicator of the development of resistance in equine nematodes.
Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

4.5 SPECIAL PRECAUTIONS FOR USE

Special precautions for use in animals

To avoid overdosing, care should be taken to accurately dose foals, especially low body weight foals or pony foals.
Do not use the same syringe to treat more than one animal unless horses are running together or in direct contact with each other in the same premises. The veterinary medicinal product has been formulated specifically for use in horses only. Dogs or cats may be adversely affected by the concentration of moxidectin in this veterinary medicinal product if they are allowed to ingest spilled paste or have access to used syringes. In dogs and cats, neurological clinical signs (such as ataxia, muscle tremor and convulsions) and digestive clinical signs (such as hypersalivation) were recorded on very rare occasions. These adverse effects are usually transient and disappear spontaneously in most cases.

Special precautions to be taken by the person administering the product to the animals

Moxidectin and the excipients benzyl alcohol, polysorbate 80 and propylene glycol can cause allergic reactions. People with known hypersensitivity to moxidectin or any of the excipients should avoid all contact with the veterinary medicinal product.

This product can cause skin and eye irritation. Avoid direct contact with skin and eyes. Wear protective gloves when handling the veterinary medicinal product. Wash hands after use. In case of skin or eye contact, rinse immediately with a large amount of water. If symptoms persist, seek medical advice and show the package leaflet or the label to the physician.
Do not smoke, drink or eat while handling the product.

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. In order to reduce the emission of moxidectin to surface water and based on the excretion profile of moxidectin when administered as the oral formulation to horses, treated animals should not have access to watercourses during the first week after treatment.

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 horses with the product, levels of moxidectin that are potentially toxic to dung beetles and flies may be excreted over a period of more than 1 week and may decrease dung fauna abundance.
• Moxidectin is inherently toxic to aquatic organisms including fish. The product should be used only according to the label instructions.

4.6 ADVERSE REACTIONS (FREQUENCY AND SERIOUSNESS)

Ataxia, depression, abdominal pain, muscle tremor, flaccid lower lip and swelling of the muzzle could be observed on very rare occasions in young animals. These adverse effects are usually transient and disappear spontaneously in most cases. In case of very high worm burdens, destruction of the parasites may cause a mild transient colic and loose faeces in the treated horse.

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).

4.7 USE DURING PREGNANCY, LACTATION OR LAY

The veterinary medicinal product has been shown to be safe for use in pregnant and lactating mares.

4.8 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS

The effects of GABA agonists may be increased by moxidectin.

4.9 AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

For oral use. A single dose of 400 µg moxidectin/kg bodyweight should be administered orally using the calibrated syringe.
Before the first dose, hold the syringe with the capped end pointing to the left so that the weight measurements and tick marks (small black lines) can be seen. Set the syringe to zero by moving the dial ring so that the left side is set at the first full black mark and depress the plunger, safely discarding any paste that is expelled.
To dose the veterinary medicinal product, hold the syringe as previously described. Each tick mark relates to 25 kg of body weight and to 10mg moxidectin. Turn the dial ring until the left side of the ring lines up with the weight of the animal. The accuracy of the dosing device should be thoroughly checked.

To ensure a correct dosage, the body weight should be determined as accurately as possible. Use of a scale or weight tape is recommended. Underdosing could result in ineffective use and may favour resistance development.
A single syringe treats a 700 kg horse.
Replace cap after use.

4.10 OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES), IF NECESSARY

Adverse reactions may occur at 2 times the recommended dose in foals and 3 times the recommended dose in adults. The symptoms are depression, inappetence, ataxia and flaccid lower lip in the 8 to 24 hours following treatment. Symptoms of moxidectin overdose are the same as those observed in very rare occasions at the recommended dosage. In addition, hypothermia and lack of appetite may occur. There is no specific antidote.

4.11 WITHDRAWAL PERIOD(S)

Meat and offal: 32 days.
Not authorized for use in animals producing milk for human consumption.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Endectocides (milbemycins)
ATC Vet code : QP54AB02

5.1 PHARMACODYNAMIC PROPERTIES

Moxidectin is a parasiticide active against a wide range of internal and external parasites and is a second generation macrocyclic lactone of the milbemycin family. Moxidectin interacts with GABA and glutamate gated chloride channels. The net effect is to open the chloride channels on the postsynaptic junction to allow the inflow of chloride ions and induce an irreversible resting state. This results in flaccid paralysis and eventual death of parasites exposed to the drug.
The exact mechanisms of parasite resistance to moxidectin have not been elucidated. A resistance mechanism involving metabolism by p-glycoproteins and efflux from the cells by ABC transporters has been proposed for ivermectin and a similar mechanism is thought to play a role in moxidectin resistance. However, parasites resistant to ivermectin are known to show some degree but not complete cross-resistance to moxidectin. It has been proposed that the reason for the incomplete cross-resistance is that there are multiple avenues for moxidectin action in target parasites that may include receptors other than the Glutamate-gated Chloride channels.
The veterinary medicinal product is effective against benzimidazole resistant strains of cyathostomes.

5.2 PHARMACOKINETIC PARTICULARS

Moxidectin is absorbed following oral administration with maximum blood concentrations being achieved 8 hours post application.
Bioavailability by the oral route is 40%. The drug is distributed throughout the body tissues but due to its lipophilicity it is selectively concentrated in the fat.
The elimination half life is 28 days.
Moxidectin undergoes partial biotransformation by hydroxylation in the body and the only significant route of excretion is the faeces.

5.3 ENVIRONMENTAL PROPERTIES

Moxidectin fulfils the criteria for a (very) persistent, bioaccumulative and toxic (PBT) substance. In particular, in acute and chronic toxicity studies with algae, crustaceans and fish, moxidectin showed toxicity to these organisms, yielding the following endpoints:

Organism		EC_{50}	NOEC
Algae	*S. capricornutum*	>86.9 µg/l	86.9 µg/l
Crustaceans (Water fleas)	*Daphnia magna* (acute)	0.0302 µg/l	0.011 µg/l
	Daphnia magna (reproduction)	0.0031 µg/l	0.010 µg/l
Fish	*O. mykiss*	0.160 µg/l	Not determined
	L. macrochirus	0.620 µg/l	0.52 µg/l
	P. promelas (early life stages)	Not applicable	0.0032 µg/l
	Cyprinus carpio	0.11 µg/l	Not determined

EC_{50}: the concentration which results in 50% of the test species individuals being adversely affected, i.e. both mortality and sub-lethal effects.
NOEC: the concentration in the study at which no effects are observed.

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, all precautions for use and disposal must be adhered to.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Butylhydroxytoluene
Disodium edetate (E386)
Poloxamer 407
Simeticone
Disodium phosphate (E339(ii))
Sodium dihydrogen phosphate dihydrate
Propylene glycol (E1520)
Polysorbate 80
Water, purified

6.2 MAJOR INCOMPATIBILITIES

Not applicable.

6.3 SHELF-LIFE

Shelf-life of the veterinary medicinal product as packaged for sale: 21 months.
Shelf-life after first opening the immediate packaging: 6 months.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C.

6.5 NATURE AND COMPOSITION OF IMMEDIATE PACKAGING

A white High Density Polyethylene (HDPE) prefilled oral syringe and dial-a-dose plunger with 25 kg bodyweight graduations, and Low Density Polyethylene (LDPE) cap, containing 14.8g of gel.

Package sizes:
Box containing 1 syringe.
Container with 10 individually boxed syringes.
Container with 20 individually boxed syringes.
Container with 20 syringes (loose).
Container with 48 syringes (loose).

Not all pack sizes may be marketed.

6.6 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM THE USE OF SUCH PRODUCTS

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.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

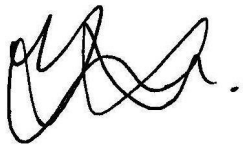
Vm 50146/5002

9 DATE OF FIRST AUTHORISATION

24 January 2023

10 DATE OF REVISION OF THE TEXT

January 2023



Approved: 24 January 2023