Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cydectin TriclaMox 5 mg/ml + 200 mg/ml Pour-on Solution for cattle.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

For a full list of excipients, see section 6.1.

Each ml contains:

Active substances

Moxidectin 5.0 mg

Triclabendazole 200.0 mg

Excipients

Butylhydroxytoluene (E321) 5.0 mg

3 PHARMACEUTICAL FORM

Pour-on solution.

A clear, amber liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

Each ml contains:

Active substances

Moxidectin 5.0 mg

Triclabendazole 200.0 mg

Excipients

Butylhydroxytoluene (E321) 5.0 mg

4.2 Indications for use, specifying the target species

In cattle:

Treatment of mixed trematode (fluke) and nematode infections and certain arthropod infestations caused by

moxidectin and triclabendazole sensitive strains:

The product has a persistent effect in preventing re-infection by Ostertagia ostertagi and by Dictyocaulus viviparus for

5 weeks after a single dose.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance(s) or to any of the excipient(s).

Parasite Adult stage Inhibited stages

NEMATODES L4

Gastro-intestinal nematodes:

Haemonchus placei

Ostertagia ostertagi

Trichostrongylus axei

Nematodirus helvetianus

Cooperia oncophora

Cooperia punctata

Oesophagostomum radiatum

Bunostomum phlebotomum

Respiratory tract nematode:

Dictyocaulus viviparus

TREMATODES

Liver fluke: 6 - 8 weeks

immatures

Fasciola hepatica

ECTOPARASITES

Linognathus vituli

Bovicola bovis

Solenopotes capillatus

4.4 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 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.

In 2010, no confirmed resistance to moxidectin in cattle parasites has been reported in Europe, however, resistance to

other macrocyclic lactones (MLs) has been reported mainly in Cooperia oncophora in some European countries, and

resistance to moxidectin has been reported in the Southern Hemisphere. Resistance to other MLs in some strains of

Cooperia spp. can imply concurrent resistance to Moxidectin. Resistance to triclabendazole has been reported in

Fasciola hepatica in cattle in some European countries. Triclabendazole resistant F. hepatica hosted in sheep can be

transferred to cattle grazing the same pasture. 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 limit further selection for resistance to anthelmintics.

This product should not be used for the treatment of single infections.

It has been shown that rainfall immediately before or within 2 hours after treatment will not affect the efficacy of the

product.

4.5 Special precautions for use

i. Special precautions for use in animals

This product has been formulated specifically for pour-on administration for cattle and must not be given by any other

route of administration or to any other species.

All animals in a group should be treated.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to

animals

Wear gloves, protective work clothing and safety glasses when using the product

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

Avoid direct contact with skin and eyes

Wash hands after use

If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.

People with known hypersensitivity to the active substance should not handle the product. If irritation persists, seek

medical advice and show the label to the doctor.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product is safe for use in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For external use only.

0.5 mg moxidectin/kg body weight and 20 mg triclabendazole/kg body weight (equivalent to 1 ml of solution for 10 kg)

and as a single topical application.

To be administered directly to the hair and skin along the midline of the back of the animal from the withers to the tail

head.

Apply to clean healthy skin.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the

dosing device should be checked. If animals are to be treated collectively rather than individually, they should be

grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Shake before use.

Directions for using the Squeeze-Pour System (500 ml and 1 litre bottles only) :

Step 1: Remove screw cap from dispensing chamber only. Remove foil seal.

Step 2: Gently squeeze the bottle to fill the measuring chamber with the required amount of liquid.

Step 3: Pour the measured volume of fluid from the chamber onto the animal as directed.

Repeat steps 2 and 3 for subsequent animals

Step 4: Reapply the screw cap to the dispensing chamber after use.

Directions for using a pour-on applicator (2.5 and 5 litre backpack):

Connect the pour-on applicator to the backpack as follows:

Attach the open end of the draw-off tubing to the cap with the stem.

Replace shipping cap with the cap that has the draw-off tubing. Tighten the draw-off cap.

Gently prime the pour-on applicator, checking for leaks.

Follow manufacturer's directions for correct use and care of equipment.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Signs of overdoses have not been seen at 5 times the recommended dose. However, if they do occur they should

be consistent with the mode of action of moxidectin and would be manifested as transient salivation, depression,

drowsiness and ataxia. Treatment is not generally necessary and recovery is generally complete within 24 to 48 hours.

There is no specific antidote.

4.11 Withdrawal Period(s)

Meat and offal: 143 days

Milk: Do not use in cattle of any age intended to produce milk for human consumption.

Due to the significant likelihood of cross-contamination of non-treated animals with this product due to grooming

(licking), treated animals should be housed separately from non-treated animals throughout the withdrawal period.

Non-compliance with this recommendation may lead to residues violations in non-treated animals.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic product, endectocides

ATC vet code: QP54AB52, moxidectin combination

5.1 Pharmacodynamic properties

Moxidectin is an endectocide active against a wide range of internal and external parasites and is a second generation

macrocyclic lactone of the milbemycin family. Its principal mode of action is interfering with neuromuscular

transmission of the GABA (gamma amino butyric acid)-gated or glutamate-gated chloride channels. Moxidectin

stimulates the release of GABA and increases its binding to the postsynaptic receptors, and binds to the glutamategated

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.

Triclabendazole is a flukicide belonging to the benzimidazole group of anthelmintics. It is well established that

benzimidazole anthelmintics selectively bind to -tubulin, thus causing the depolymerisation of microtubules and the

subsequent disruption of microtubule-based processes in helminths.

5.2 Pharmacokinetic properties

Moxidectin is distributed throughout the body tissues but due to its lipophilicity the highest drug concentrations are

obtained in fat tissue. Moxidectin undergoes biotransformation by hydroxylation. The only significant route of

excretion is the faeces. The main pharmacokinetic parameters of moxidectin when administered as pour-on in the final

combined formulation of this product were the following: AUClast 50.9 ng.d.mL-1, Cmax 4.69 ng.mL-1, Tmax 8.7 d,

MRT 10.74 d .

The majority of the oral dose of triclabendazole in rats, sheep, goats and rabbits is eliminated in faeces after 6-10 days,

as unchanged drug or products of biliary excretion. Urinary excretion is minimal. Sulphone, sulphoxide, ketone and 4-

hydroxy triclabendazole derivatives are the main metabolites identified in plasma. Plasma kinetic studies of sulfoxide

and sulfone derivatives in various species after oral administration showed the sulfoxide to predominate in rabbits,

sheep and humans, and the sulfone in the horse, dog and cattle. The main pharmacokinetic parameters of

triclabendazole sulfoxide when administered in the final combined formulation of this product were: AUClast 26.9

µg.h.mL-1, Cmax 2.92 µg.mL-1, Tmax 3.3 d, MRT 9.72 d. The main pharmacokinetic parameters of triclabendazole

sulfone when administered in the final combined formulation were: AUClast 110.2 µg.h.mL-1, Cmax 7.78 µg. mL-1,

Tmax 12.9 d, MRT 12.98 d.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)

-Hexalactone

Cineole

Caprylocaproyl Macrogolglycerides

6.2 Incompatibilities

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

medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

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

6.4 Special precautions for storage

Do not store above 25°C.

Protect from light.

Do not freeze.

If accidentally frozen, shake vigorously before use.

6.5 Nature and composition of immediate packaging

0.5, 1, 2.5 and 5 litre HDPE containers with polypropylene screw cap and polyethylene inner seal.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be

disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited

25/28 North Wall Quay

Dublin 1

Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/019/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5th April 2012

10 DATE OF REVISION OF THE TEXT

January 2014