

[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ezeepour 2.5% w/v Pour on Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Cypermethrin Technical (93% w/w; cis/trans isomers 50 : 50) 2.5% w/v

Excipient: Qualitative composition of excipients and other constituents
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Myritol (Triglyceride, medium chain)

An oily-based clear, pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For control of lice and flies.

3.3 Contraindications

Do not treat calves under 7 days of age.

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

As per the special safety precautions to be taken by the person administering the product to animals listed below.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product should be administered in a well-ventilated area. Personal protective equipment consisting of protective clothing including rubber gloves, should be worn when handling the veterinary medicinal product. Any accidental splashes should be washed off immediately.

Do not eat, drink or smoke when applying the veterinary medicinal product. Wash hands and any exposed skin immediately after application has finished.

3.6 Adverse events

Undetermined frequency (cannot be estimated from the available data)
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Discomfort ¹

1. Slight signs may be observed during the 48 hours following application. These side-effects are only temporary and have no long-term implications.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing

authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The active ingredient has a low oral activity and very little transdermal absorption is expected. To date there have been no reported complications in pregnancy or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For topical administration as a pour-on solution.

LICE CONTROL

A single 10 ml dose is normally sufficient to control lice. A few lice may survive on a small minority of animals. In cases of heavy challenge, if necessary, a repeat dose may be applied after 4 weeks.

Remove the cap from the chamber and gently squeeze the required amount into the chamber. Release the pressure from the container and pour as directed.

The 10 ml dose should be applied at an even rate along the backline from the crown of the head to the top of the rump.

FLY CONTROL

Apply a single 10ml dose at the onset of the fly season and repeat as necessary at 5 to 8 week intervals. Frequency of administration may, however, have to be varied depending on the level and type of infestation.

The 10 ml dose should be applied at an even rate along the back line from the crown of the head to the top of the rump.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Care should be taken not to overdose. Overdosing may invalidate the stated milk and meat withholding times as in 3.12 below.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and Offal: 10 days

Milk: Zero hours. Cows should be treated immediately after milking to allow as long a time as possible to elapse before the next milking.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP53AC08.

4.2 Pharmacodynamics

Cypermethrin is a synthetic pyrethroid insecticide used for both crop protection and to control ectoparasites on livestock.

Cypermethrin is a contact poison, having a rapid paralytic action on insects, preceded by muscular excitation and convulsions. The pyrethroids have sufficient stability to have a prolonged effect when applied to the animal.

4.3 Pharmacokinetics

Cypermethrin is not systemically active when used as a “pour-on” preparation. When applied in this manner, the product spreads over the surface of the animal.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Incompatible with alkali materials.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25°C. Store in the original container away from foodstuffs.

5.4 Nature and composition of immediate packaging

High density polyethylene multi-dose 500 ml (with graduated measuring compartment) and 2.5L container. Each container is sealed with an aluminium tamper-evident seal and a plastic cap. Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

The veterinary medicinal product should not enter water courses as cypermethrin may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or used containers.

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited.

7. MARKETING AUTHORISATION NUMBER(S)

VPA: 22033/019/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 01 October 1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10 CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).