SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zermasect Cattle Pour-On Solution 15 g/litre

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Alphacypermethrin 15 g/litre

Excipient(s):

Benzoic acid 1.0 g/litre

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour-on solution. Yellow liquid free from solids.

4. CLINICAL PARTICULARS

4.1. Target species

Cattle

4.2. Indications for use, specifying the target species

For topical application to control flies and lice on cattle.

4.3. Contraindications

None

4.4. Special warnings

None.

4.5. Special precautions for use

i) Special precautions for use in animals

For external use only.

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

Wear waterproof apron and boots and impervious gloves when applying the product and when handling treated animals.

Wash splashes from skin and eyes immediately. Remove heavily contaminated clothing and wash before re-use. Wash hands and exposed skin before eating, drinking or smoking and after work.

4.6. Adverse reactions (frequency and seriousness)

Signs of discomfort may be exhibited by some animals after treatment. This will not last longer than 48 hours and will have no lasting effect on the animal.

4.7. Use during pregnancy, lactation or lay

The product can be safely used during pregnancy and lactation.

4.8. Interaction with other medicinal products and other forms of interaction

None known.

4.9. Amounts to be administered and administration route

All cattle 10ml per animal.

Application Administration:

Apply a single 10ml dose with the dispenser pack or with an applicator gun, from the crown of the head down the neck and along the middle of the back of the animal.

Fly Control:

To control biting and nuisance flies, treatment should be repeated as necessary. Frequency of application will depend on the numbers and species of flies present; normally nuisance flies on the head and face can be controlled for up to 4/5 weeks and for the biting horn fly for up to 8 weeks.

Lice Control:

To control sucking and biting lice. One application treatment will normally eradicate all the lice. If a few lice survive on individual animals, it may be necessary on very rare occasions to re-treat an animal.

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

Zermasect is of low toxicity and acute poisoning is unlikely to occur.

4.11. Withdrawal periods

Meat: 28 days. Milk: zero hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ectoparasiticides for topical use, incl.

insecticides.

ATCVet code: QP53AC08 cypermethrin

5.1. Pharmacodynamic properties

Alphacypermethrin is a non-systemic pyrethroid insecticide with contact and stomach action. It acts on the central and peripheral nervous system in very low doses.

5.2. Pharmacokinetic particulars

None known.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzoic Acid Arlatone T Dioctyl Adipate (DOA) Maize Oil

6.2. Incompatibilities

None known.

6.3. Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4. Special precautions for storage

Store in tightly closed original container.

Do not store above 25°C.

Store away from food, drink and animal feedstuffs.

6.5. Nature and composition of immediate packaging

Pack size: 250ml, 500ml and 1 litre.

Container/closure: High density polyethylene squeeze and pour pack with

internal calibrated chamber capable of measuring 10ml.

Pack size: 1 litre

Container/closure: High density polyethylene backpack with polypropylene

screw cap and aluminium foil seal.

Dosing device: Simcro Tech 10 ml measuring cap or applicator gun.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used containers.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited 1st Floor, Birchwood Building Springfield Drive Leatherhead Surrey KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4167

9. DATE OF FIRST AUTHORISATION

07 May 2008

10. DATE OF REVISION OF THE TEXT

November 2020

Approved 06 November 2020