

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Renegade 15 mg/ml Pour on Emulsion for Cattle.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

		<u>Quantity:</u>
<u>Active Substance:</u>		
Alpha cypermethrin	15	mg
<u>Excipients:</u>		
Benzoic acid (E210)	1	mg
(as antimicrobial preservative)		

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pour-on emulsion.
A clear yellow liquid.

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

Do not use in animals with known hypersensitivity to the active substance.

4.4 Special warnings for each target species

For external use only.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Protective gloves should be worn when applying product.
Wash splashes from skin or 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. However, to avoid the possibility of this resulting in abortion/premature calving, the product should not be used within the 4 weeks before parturition.

4.7 Use during pregnancy, lactation or lay

This product should not be used within the 4 weeks before parturition.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For topical application only.

All cattle: 10 ml per animal.

Application Administration:

Apply a single 10 ml 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 at intervals of not less than 4 weeks. 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 weeks and biting flies for up to 8 weeks.

Lice control:

To control sucking and biting lice. One application will normally eradicate all the lice. In case of heavy challenge, if necessary, a repeat dose can be applied after 4 weeks.

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

The product has a high safety margin.

4.11 Withdrawal Period(s)

Meat and offal: 14 days

Milk: Zero hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, incl. insecticides, pyrethroids

ATCvet code: QP53AC

5.1 Pharmacodynamic properties

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyoxyethylene 40 Sorbitol Septaoleate
Di-octyl Adipate
Benzoic Acid
Corn Oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C.

Store in original container, tightly closed, in a safe place away from animal feedstuffs.

6.5 Nature and composition of immediate packaging

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

Container/closure: High density polyethylene squeeze and pour pack with internal calibrated chamber capable of measuring 10 ml volumes.

Not all pack sizes may be marketed here.

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

The product is harmful to fish. Do not contaminate ponds, waterways or ditches with the product or used containers. Wash out containers thoroughly and dispose of safely.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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 10438/080/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st September 1999

Renewal of last authorisation: 30th September 2010

10 DATE OF REVISION OF THE TEXT

September 2013