

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flectron Fly Tags 935 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tag contains:

Active Substance:

Cypermethrin (as Cypermethrin pyrethroid) 935 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ear tag. Heptagonal, amber, translucent tag with a pliable, dry, impregnated blotter type PVC resin.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For season long control of nuisance and biting flies including:

Nuisance flies:

Face fly (*Musca autumnalis*)

Head fly (*Hydrotea irritans*)

Biting flies:

Horn fly (*Haematobia irritans syn Lyperosia irritans*)

Stable fly (*Stomoxys calcitrans*)

Cattle biting fly (*Haematobia stimulans syn Haematobosca stimulans*)

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance

4.4 Special warnings for each target species

None.

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

- Rubber gloves should be worn when handling the fly tags.
- Tags should be removed before cattle leave the farm for slaughter.
- Do not burn, can produce harmful vapour.
- Wash hands and exposed skin before meals and after work.
- Avoid smoking when handling the fly tags.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation

4.8 Interaction with other medicinal products and other forms of interactions

None known

4.9 Amounts to be administered and administration route

Flectron eartags can control flies for up to 4 months when used as directed. For maximum benefit they should therefore be applied at the beginning of the season before fly populations build up. For complete control the entire herd should be tagged.

One tag per animal is usually sufficient to achieve acceptable levels of fly control. However, where head and face fly attack is very severe, two tags may be necessary, one on each ear.

Flectron eartags should be attached to the ear as follows:

Load stud and tag into the applicator according to the manufacturer's directions. Restrain the animal, preferably in a crush, so that the ear can be reached easily. Position the point of the fixing stud between the blood vessels in an area of firm tissue halfway between the head and the tip of the ear, with the fly tag on the back of the ear. A position between the second and third rib of the ear is ideal.

Depress the applicator until a click is heard. This means the tag and the fixing are firmly secured.

If a tag is lost during the season it is usually because of poor application. Flectron ear tags will remain flexible and active for a season.

Flectron ear tags are not recommended for fly control on cattle kept in feed lots or in animal housing.

Tags should be removed at the end of each fly season and before cattle go for slaughter. The neck of the stud behind the ear can be cut with round-nosed scissors. The new tag can be applied through the hole left by the previous one

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

None.

4.11 Withdrawal period(s)

Meat and offal: Zero days.

Milk: Zero hours.

Tags should be removed before cattle leave the farm for slaughter.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use, pyrethroids

ATCvet code: QP53AC08

5.1 Pharmacodynamic properties

The formulation for Flectron is devised so that the active ingredient, cypermethrin, is slowly released onto the surface of the tag. As the exposed chemical is removed, more cypermethrin is released onto the surface. Thus the tag acts as a constant reservoir of insecticide throughout the season.

The active ingredient is lipophilic and is thus strongly bound to the sebum or natural oil present in the animal's coat and on the surface of the skin. Natural body movements - grooming and rubbing against other cattle - transfer the insecticide onto the

hairs of the coat. This disperses the active ingredient all over the animal, effectively giving the whole body protection against flies within 24 to 48 hours. The binding of the cypermethrin onto the sebum ensures a high degree of rain fastness.

Cypermethrin acts principally as a contact insecticide. Flies therefore have to come into contact with the chemical to be killed so it is normal to see a few on a tagged animal.

Flies landing on a tagged animal will pick up the insecticide on their feet or bodies. They then leave quickly as the chemical acts as a repellent. The flies normally leave before they have had time to bite, feed or otherwise annoy the animal. As the chemical on the flies is absorbed they become hyperactive and die within a few minutes.

Biting flies appear to be controlled more easily than nuisance flies, possibly because biting flies burrow under the hair, and thus pick up a lethal dose of cypermethrin on their bodies as well as on their feet.

5.2 Pharmacokinetic particulars

Trials have shown that continuous release of active ingredient from the tag maintains adequate protection of the animal throughout the whole of the fly season - i.e. up to four months under temperate European conditions

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

LZC525 stabiliser
Polyvinyl chloride
Di-octyl adipate
Filing stud (Polyether Polyurethane)

6.2 Major 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

Store in the original package. Keep the package tightly closed.
Store below 25°C.

6.5 Nature and composition of immediate packaging

10 heptagonal tags packed in a plastic bag contained in an outer carton box.

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 materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Do not burn fly tags as they can produce harmful vapour. Harmful to bees and fish. Do not contaminate ponds, waterways and ditches with fly tags and containers.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/034/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1999
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

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