

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Electron Fly Ear Tags for Cattle 935 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Each 11g tag contains:

<u>Qualitative composition</u>	<u>Quantitative composition mg</u>
Cypermethrin 100% (cis:trans 50:50)	935.0

Excipients:

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 the control of flies on cattle.

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*).

While the five fly species listed above constitute the majority found on cattle in Western Europe, there are many other species both within and outside Europe against which tags may provide some protection. These include:

Warble (*gad*) fly (*Hypoderma* sp)
Horse fly (*Tabanus bovinus*)
Clegs (*Haematopota pluvialis*)
Screw-worm (*Callitroga* sp)
Blow fly (*Lucilia* sp)

Other species reported as forming a minor component of the fly population on cattle monitored during trials of tags include:

Sweat fly (*Morellia simplex*)

Black fly (*Simulium reptans*)

Lesser house fly (*Fannia conicularis*)

Electron ear tags provide protection throughout the fly season. 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.

4.3 Contraindications

None

4.4 Special warnings

The best position for the tag is between the second and third rib of the ear. Electron ear tags are not recommended for fly control on cattle kept in feed lots or in animal housing. For external use only.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

ii) 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. Do not smoke, eat or drink while handling the product. Do not burn the product as a harmful vapour can be produced. Wash hands and exposed skin before meals and after work. Keep away from food and drink including animal feeding stuffs.

4.6 Adverse reactions (frequency and seriousness)

This product belongs to the pyrethroid group. Possible undesirable effects can be irritation and allergic reactions on the skin.

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

Flectron ear tags should be attached to the ear as follows:

Load stud and tag into the applicator. Always dip the loaded applicator into disinfectant solution before each application. Any skin compatible disinfectant may be used. This assists application, helps prevent spread of infection, aids hygiene and promotes healing. Restrain the animal, preferably in a crush, so that the ear can be reached easily. Position the point of the fixing stud in a central position 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. Thick sections of the ear should be avoided.

Depress the applicator until a click is heard. This means the tag and the fixing are firmly secured. After fixing, pull the stud and tag firmly apart as far as possible. A correctly fixed tag will hold firm. Do not push the tag and stud back together, as this can lead to compression of the ear tissue. The two should swing freely in the ear.

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.

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 the following season.

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

Not applicable.

4.11 Withdrawal periods

Meat – Zero days

Milk – Zero hours

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

5. PHARMACOLOGICAL 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.

ATCVet Code: QP53AC08

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

LZC525 Stabiliser
Dioctyl adipate
Polyvinylchloride

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years

6.4 Special precautions for storage

Store in tightly closed original container.
Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Primary container consists of a low density polyethylene bag containing 10 ear tags and fastening studs, which are contained in a cardboard box. Each cardboard box contains two LDPE bags.

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.

Harmful to fish and aquatic life. Do not contaminate ponds, waterways and ditches with the tags or empty containers.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

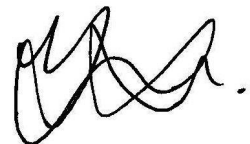
Vm 42058/4069

9. DATE OF FIRST AUTHORISATION

26 May 1993

10. DATE OF REVISION OF THE TEXT

April 2021

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 08 April 2021