## 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

#### **Excipients:**

Qualitative composition of excipients and other constituents
Epoxidized soybean oil stabiliser
Polyvinyl chloride

Di-octyl adipate

Filing stud (Polyether Polyurethane)

Ear tag.

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

### 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle.

### **3.2** Indications for use for each 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)

### **3.3** Contraindications

Do not use in cases of hypersensitivity to the active substances.

#### 3.4 Special warnings

None.

#### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

Not applicable.

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

Personal protective equipment consisting of rubber gloves should be worn when handling the veterinary medicinal product.

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

Wash hands and exposed skin before meals and after work.

Avoid smoking when handling the fly tags.

There are no side effects to operators if used as recommended. If skin is affected wash with soap and water. If swallowed do not induce vomiting. Obtain medical attention immediately.

#### Special precautions for the protection of the environment:

Do not burn fly tags as they can produce harmful vapour. Harmful to bees and fish.

#### 3.6 Adverse events

None known.

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 package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

#### Pregnancy and lactation:

Can be used during pregnancy and lactation.

### **3.8** Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

The veterinary medicinal product 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.

The veterinary medicinal product 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. The veterinary medicinal product will remain flexible and active for a season.

The veterinary medicinal product is 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.

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

None.

**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: Zero days. Milk: Zero days.

#### 4. PHARMACOLOGICALINFORMATION

#### 4.1 ATCvet code: QP53AC08

#### 4.2 Pharmacodynamics

The formulation for the veterinary medicinal product 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.

#### 4.3 Pharmacokinetics

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.

## 5. PHARMACEUTICAL PARTICULARS

#### 5.1 Major incompatibilities

None known.

#### 5.2 Shelf life

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

#### 5.3 Special precautions for storage

Store below 25 °C. Store in the original package.

Keep the package tightly closed.

### 5.4 Nature and composition of immediate packaging

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

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

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

The veterinary medicinal product should not enter water courses as cypermethrin may be dangerous for fish and other aquatic organisms.

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

Zoetis Belgium S.A.

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/034/001

## 8. DATE OF FIRST AUTHORISATION

09/12/2013

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

14/08/2024

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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