PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Outer carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flectron[®] Fly Ear Tags for Cattle 935 mg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each PVC ear tag contains 935.0 mg cypermethrin 100% as cypermethrin technical (cis 50: trans 50).

3. PHARMACEUTICAL FORM

Ear tag

4. PACKAGE SIZE

Contents: 20 fly ear tags and fastening studs

5. TARGET SPECIES

Cattle

6. INDICATIONS

For the control of flies on cattle.

Effective for up to 5 months.

Whole body protection

7. METHOD AND ROUTE OF ADMINISTRATION

RECOMMENDATIONS FOR USE

1 or 2 tags per animal (dependent upon the severity of the infestation), fixed in the ear.

To be applied before flies become a problem. Will last for up to 5 months. For complete control the entire herd should be tagged.

GENERAL FLY CONTROL Use one fly tag per animal

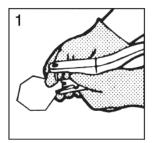
SEVERE HEAD AND FACE FLY CONTROL

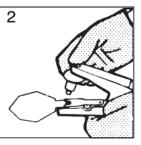
Where head and face fly attach is severe, and disease incidences are thus likely to be high: tag both ears.

DIRECTIONS FOR FIXING FLY TAGS

Flectron[®] Fly Ear Tags for Cattle 935 mg should be applied to the ear using the Allflex[®] tagging system.

Using the Allflex® Application Pliers position the fixing stud between the blood vessels, in a central area of firm tissue, halfway between the head and tip of the ear, with the fly tag on the back of the ear. Apply as follows:



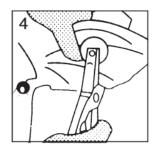


Place the fly tag under the clip by depressing the lever.

Slide the male button onto the pin until it projects through the tip.

3

Always dip into disinfectant solution. This helps prevent the spread of infection, assists application and promotes healing.



Centre, then apply through the ear halfway between ear tip and head, with the fly tag on the back of the ear, taking care to avoid confusion with other ear marks.

If two fly tags are used, place one in each ear.

Read the package leaflet carefully before applying the tags.

8. WITHDRAWAL PERIOD

Meat – Zero days.

Milk – Zero hours.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet carefully before applying the tags.

Warning – remove fly tags from cattle after use & dispose of safely.

Remove tags before cattle leave the farm for slaughter.

User Warnings:

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.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container.

Do not store above 25°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

HARMFUL TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the tags or empty containers.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-VPS

To be supplied only on veterinary prescription.

For animal treatment only.

For external use only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4069

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:

Flectron[®] Fly Ear Tags for Cattle 935 mg

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MA Holder:

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

Manufacturer responsible for batch release:

River Manufacturing Limited 61 Windmill Road Sudbury on Thames Middlesex TW16 7DT

or

Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flectron[®] Fly Ear Tags for Cattle 935 mg

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each PVC tag contains 935 mg cypermethrin 100% as cypermethrin technical (cis 50: trans 50).

4. INDICATIONS

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) and 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*) and Lesser house fly (*Fannia coniculars*).

Flectron 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.

5. CONTRAINDICATIONS

Tags must be removed before cattle leave farm for slaughter.

6. ADVERSE REACTIONS

-

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

Directions for fixing:

• Restrain the head of the animal. The use of a crush is ideal.

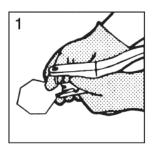
• Always dip the loaded applicator into disinfectant solution before each application. Any skin-compatible disinfectant may be used. This assists application, helps prevent spread of infection, aids hygiene and promotes healing.

• Ensure that the tag is placed **centrally**, in an area of firm tissue between the second and third rib, with the fly tag on the back of the ear. Thick sections of the ear should be avoided as should blood vessels. The tag should swing freely in the ear.

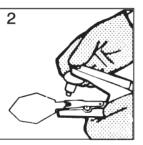
• When applying, depress the applicator fully and sharply so that a 'click' is heard. This ensures correct fixing.

• **Check!** 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.

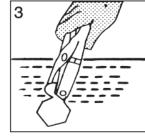
• Full protection can be expected within 24-48 hours of fixing.



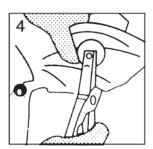
Place the fly tag under the clip by depressing the lever.



Slide the male button onto the pin until it projects through the tip.



Always dip into disinfectant solution. This helps prevent the spread of infection, assists application and promotes healing.



Centre, then apply through the ear halfway between ear tip and head, with the fly tag on the back of the ear, taking care to avoid confusion with other ear marks.

Removal

Remove tags at the end of the fly season. Cut the stem of the stud between the tag and the back of the ear with a pair of strong round nosed scissors. The small hole left in the ear, if not healed over at the start of the following season, can be used for re-tagging.

10. WITHDRAWAL PERIOD(S)

Meat - Zero days

Milk – Zero hours

11. SPECIAL STORAGE PRECAUTIONS

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

Keep container in outer carton.

12. SPECIAL WARNINGS

For external use only.

Rainfall

Rain will not remove the active ingredient from the tag. When on the animal, the active ingredient locks onto the oils on the coat. This results in a higher degree of rainfastness. Following rain, fly activity may temporarily increase due to further fly emergence.

User Warnings:

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.

Keep out of the sight and reach of children.

For animal treatment only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

Summer Mastitis and New Forest disease:

Flies are associated with the transmission of these diseases. Fly control can help reduce the disease incidence. Fly-borne diseases can have incubation periods of variable lengths (weeks rather than days); symptoms which appear in mid to late summer may be due to an infection transmitted by flies earlier in the season, therefore early attention to fly control methods is important. However, the use of any method of fly control does not mean that any other precautions can be omitted (e.g. infusion of heifers and dry cows with long acting antibiotics, separation of stock with New Forest disease etc.).

POM-VPS

To be supplied only on veterinary prescription.

Vm 42058/4069

Revised: December 2020 AN: 01062/2020

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Approved 21 December 2020