ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidacloprid EU Pharma 80 mg Spot-on solution for Large Cats and Large Pet Rabbits
imidacloprid

2. STATEMENT OF ACTIVE SUBSTANCES

Imidacloprid 80 mg

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1 x 0.8 ml
2 x 0.8 ml
3 x 0.8 ml
4 x 0.8 ml
6 x 0.8 ml

5. TARGET SPECIES

Cats and pet rabbits

6. INDICATION(S)

Prevention and treatment of flea *(Ctenocephalides felis)* infestations in cats of 4 kg body weight and greater.
Treatment of flea infestations in rabbits of 4 kg body weight and greater.
Fleas are killed within one day following treatment. One treatment prevents further flea infestation for three to four weeks on cats and up to one week on pet rabbits.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Do not use on rabbits intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before every use for full instructions and user warnings.

User Warnings
Store pipettes in the original packaging until ready to use.
This product can cause mucous membrane, skin and eye irritation.
Therefore, contact of the product with mouth, skin and eyes should be avoided.
This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).
People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the product.
Do not smoke, drink or eat during application.
If contact with the skin occurs, wash hands with soap and water.
If the product gets into eyes, the eyes should be thoroughly rinsed with clean water. If skin or eye irritation persists, or the product is accidentally swallowed, seek medical advice.

Do not stroke, groom or play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.
Dispose of used pipettes immediately.
Wash hands after use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

EU Pharmaceuticals Ltd.
37 Geraldine Road
London
SW18 2NR

16. MARKETING AUTHORISATION NUMBER(S)

Vm 39787/4091

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidacloprid EU Pharma 80 mg Spot-on solution for Large Cats and Large Pet Rabbits
imidacloprid

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Imidacloprid 80 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.8 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD(S)

Do not use on rabbits intended for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Pipette}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidacloprid EU Pharma Spot-on 

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Imidacloprid 80 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.8 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

LOT {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Imidacloprid EU Pharma 80 mg Spot-on solution for Large Cats and Large Pet Rabbits

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

Marketing authorisation holder and manufacturer responsible for batch release:
EU Pharmaceuticals Ltd.
37 Geraldine Road
London
SW18 2NR

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidacloprid EU Pharma 80 mg Spot-on solution for Large Cats and Large Pet Rabbits
imidacloprid

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

Each 1 ml contains:

Active substance:
Imidacloprid 80 mg

Excipients:
Butylhydroxytoluene (E 321) 0.8 mg

4. INDICATION(S)

Prevention and treatment of flea *(Ctenocephalides felis)* infestations in cats of 4 kg body weight and greater.
Treatment of flea infestations in rabbits of 4 kg body weight and greater.
Fleas are killed within one day following treatment. One treatment prevents further flea infestation for three to four weeks on cats and up to one week on pet rabbits.

5. CONTRAINDICATIONS

Do not treat unweaned kittens of less than 8 weeks of age.
Do not use on pet rabbits of less than 10 weeks of age.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

The product is bitter tasting and salivation may occasionally occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment.
In very rare occasions (less than 1 animal in 10,000 animals, including isolated reports) skin reactions such as hair loss, redness, itching and skin lesions may occur in cats and rabbits. Agitation has also been reported. Excessive salivation and nervous signs such as incoordination, tremors and depression have been reported but exceptionally in cats.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).>

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats and pet rabbits

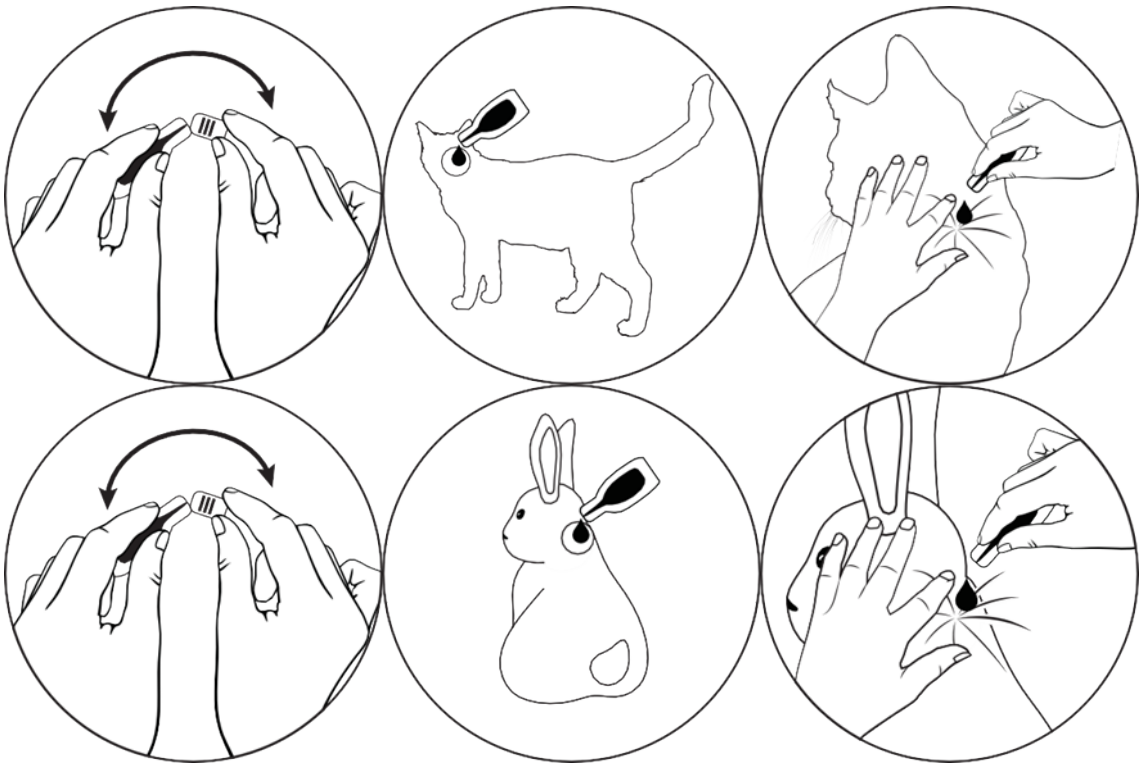
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

This product is for external use only and should not be administered orally. Animals should be weighed accurately prior to treatment.

Dosage and Treatment Schedule

Cat/Rabbit (kg body weight)	Product	Number of Pipettes	Advaprid (mg/kg body weight)
4 kg and greater	Advaprid 80 for Large Cats and Large Pet Rabbits	1 x 0.8 ml	minimum of 10

Method of administration:
Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Snap back the tip. Part the hair on the animal's neck at the base of the skull until the skin is visible.
Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot. Correct application will minimise the opportunity for the animal to lick the product.



9. ADVICE ON CORRECT ADMINISTRATION

Discard any opened pipettes.

10. WITHDRAWAL PERIODS

Do not use on rabbits intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after {EXP}. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for each target species:
If signs of disease persist or appear, consult a veterinary surgeon.
Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid reduction in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended. In order to reduce further the environmental challenge, it is recommended that all cats and rabbits in the household are treated. The product remains effective if the animal

becomes wet, for example after exposure to heavy rain. However, retreatment may become necessary, depending on the presence of fleas in the environment. In these cases do not treat more frequently than once weekly.

Special precautions for use in animals:
This product is for topical use and should not be administered orally.
Apply only to undamaged skin
Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.
Do not allow recently treated animals to groom each other.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product can cause mucous membrane, skin and eye irritation.
Therefore, contact of the product with mouth, skin and eyes should be avoided.
This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).
People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the product.
Do not smoke, drink or eat during application.
If contact with the skin occurs, wash hands with soap and water.
If the product gets into eyes, the eyes should be thoroughly rinsed with clean water. If skin or eye irritation persists, or the product is accidentally swallowed, seek medical advice.

Do not stroke, groom or play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.
Dispose of used pipettes immediately.
Wash hands after use.

Pregnancy and lactation:
No reproductive toxic effects have been observed in rats and no primary embryotoxic or teratogenic toxic effects have been observed during the studies on rats and rabbits. Studies on pregnant and lactating queens and does together with their offspring are limited. Evidence so far suggests that no adverse effects are to be expected in these animals. Consult your veterinary surgeon before using in pregnant or nursing animals.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with other flea products which are applied directly onto the animal.

Overdose (symptoms, emergency procedures, antidotes):
In cats, no adverse clinical signs were produced using doses of five times the therapeutic level weekly for eight consecutive weeks.
In rabbits, no adverse clinical signs were seen using doses of up to 45 mg/kg body weight (4 times the therapeutic level) weekly for 4 consecutive weeks.

In rare cases of overdose or licking of treated fur, nervous system disorders (such as twitching, tremors, ataxia, mydriasis, miosis, lethargy) can occur in cats.
Poisoning following inadvertent oral uptake in animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

Incompatibilities:
None known.

Other precautions
The solvent in this product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Imidacloprid may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Box with 1, 2, 3, 4, 6 pipettes in individual foil sachets.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 9 July 2019