ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris 160 mg Spot-on solution for small cats
ProMeris 320 mg Spot-on solution for large cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances

Each ml contains 200 mg metaflumizone.

Each unit dose (pipette) of ProMeris delivers:

	Volume (ml)	**Metaflumizone (mg)**
ProMeris for Small Cats (≤ 4 kg)	0.80 ml	160 mg
ProMeris for Large Cats (> 4 kg)	1.60 ml	320 mg

Excipients

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution
A clear, yellow to amber solution

4. CLINICAL PARTICULARS

4.1 Target species

Cats over 8 weeks of age.

4.2 Indications for use, specifying the target species

Treatment and prevention of flea infestations (*Ctenocephalides canis and C. felis*) in cats. The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

4.3 Contraindications

Do not administer to kittens under 8 weeks of age.

4.4 Special warnings

Avoid contact with the eyes of the cat and avoid oral ingestion by the animal.

For optimum control of flea problems in a multi-pet household, all pets in the household should be treated with a suitable insecticide. In addition it is recommended to treat the environment with a suitable insecticide.

4.5 Special precautions for use

Special precautions for use in animals

In sick or debilitated animals, use only according to the benefit/risk assessment by the responsible veterinarian.

This veterinary medicinal product is for spot-on application only. Do not administer orally or via any other route.

It is important to apply the dose to an area where the animal cannot lick it off. Do not allow animals to groom each other following treatment.
Care should be taken to ensure that the content of the pipette or the applied dose does not come into contact with the eyes or mouth of the recipient and/or other animals.

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

Avoid direct contact with skin, eyes or mouth. Wash hands thoroughly after use. In case of accidental spillage onto skin, wash off immediately with soap and water. If the veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with water.

Do not smoke, drink or eat while handling the veterinary medicinal product.

Avoid direct contact with treated animals until the application site is dry.

Children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended to treat the animals during the evening. Recently treated animals are not allowed to sleep with owners, especially children.

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

4.6 Adverse reactions (frequency* and seriousness)

Hypersalivation may occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within minutes without treatment. Correct application will minimise licking of the application site.

The application of the veterinary medicinal product may produce a local, temporary oily appearance and clumping or spiking of the fur at the application site. A dry residue may also be observed. This is normal and will generally resolve within 1 – 4 days after administration. These changes do not affect the safety or efficacy of the veterinary medicinal product. In rare cases, transient irritation may occur at the site of the product application. In very rare cases temporary local hair loss may occur.

*- Very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- Common (more than 1 but less than 10 animals in 100 animals)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals)
- Rare (more than 1 but less than 10 animals in 10,000 animals)
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 interaction

None known.

4.9 Amounts to be administered and administration route

Dosage:

The recommended minimum dose is 40 mg metaflumizone/kg bodyweight, equivalent to 0.20ml/kg bodyweight. The following table defines the size of pipette to be used according to the weight of the cat

Weight Of Cat (kg)	Pipette size to be used	Volume (ml)
≤ 4	ProMeris for Small Cats	0.80
> 4	ProMeris for Large Cats	1.60

Method of administration:

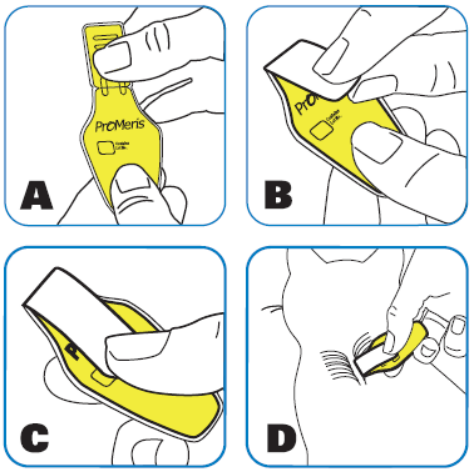
For cutaneous use only. Spot-on use.

Remove the pipette from the package. Hold the pipette upright, bend the tip of the pipette to break the tip along the scored line. The top of the tip will fold back against the pipette.

Apply the content of the pipette to a single spot on the skin of the cat's neck at the base of the skull.

Part the fur on the cat'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 to empty the entire contents.

Do not apply the veterinary medicinal product to the surface of the cat's hair coat.



Treatment schedule:

For optimal control of flea infestation, the veterinary medicinal product can be administered at 4 to 6 week intervals throughout the flea season or the treatment schedule can be based on the local epidemiological situation.
The veterinary medicinal product will prevent flea infestation for up to 6 weeks following a single administration depending on the level of environmental rechallenge.

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

No adverse effects were observed in cats aged 8 weeks and older treated 7 times at two-week intervals with 3-5 times the recommended dose.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: ATC Vet Code QP 53AX25

Metaflumizone is an ectoparasiticide belonging to the semicarbazone group of compounds. Metaflumizone is a sodium channel antagonist and disrupts nerve function resulting in paralysis and death of insects. Metaflumizone is active against fleas due to non-systemic exposure of the parasites on the skin and hair. Maximum efficacy is achieved within 48 hours.

5.2 Pharmacokinetic particulars

After topical administration at a single site on the cat's neck at the base of the skull, metaflumizone is rapidly distributed throughout the surface of the skin. Maximum concentrations in the hair were generally reached between 1 to 2 days post-treatment and gradually declined through 56 days post-treatment. Metaflumizone was still measurable in the hair 56 days following treatment. These results are consistent with laboratory efficacy studies showing activity for up to 56 days post-treatment.

After topical administration at a single site on the cat's neck at the base of the skull, metaflumizone levels in plasma were too low to allow the calculation of standard pharmacokinetic parameters.

5.3 Environmental properties

See section 6.6

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Synperonic NCA 830
Dimethyl sulfoxide
Gamma-hexalactone

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4. Special precautions for storage

Do not store above 25°C

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is packaged in individual-dose transparent plastic pipettes overpacked in an aluminium foil package. It is supplied in units of 3 pipettes per cardboard card and one or two cards per cardboard box. All blisters in a box are the same size.

Box of 1 or 2 blister card of 3 x 0.80 ml pipettes
Box of 1 or 2 blister card of 3 x 1.60 ml pipettes

Not all pack sizes may be marketed.

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.
Carefully dispose of used pipettes immediately after use.

7. MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/064/001-004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/12/2006

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Wyeth Lederle Italia S.p.A.
18, Via Franco Gorgone
95121 Catania
Italy

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. STATEMENT OF THE MRLs

Not applicable

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Pharmacovigilance system

The MAH must ensure that the system of pharmacovigilance, as described in Part I of the marketing authorisation application, is in place and functioning before and whilst the veterinary medicinal product is on the market.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box for 1 blister card -Carton box for 2 blister cards

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris 160 mg Spot-on for small cats {≤ 4 kg}

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.80 ml pipette delivers:
Active substance: 160 mg metaflumizone

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

Box of 1 blister card of 3 x 0.80 ml pipettes
Box of 2 blister cards of 3 x 0.80 ml pipettes

5. TARGET SPECIES

For cats over 8 weeks of age.

6. INDICATION(S)

For the treatment and prevention of infestations by fleas.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer to kittens under 8 weeks of age. Consult your veterinarian before using the veterinary medicinal product on sick or debilitated cats.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

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

Dispose of waste material in accordance with local requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder
Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/064/001 – 1 blister card of 3 pipettes of 0.80 ml
EU/2/06/064/002 – 2 blister cards of 3 pipettes of 0.80 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box for 1 blister card
Carton box for 2 blister cards

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris 320 mg Spot-on for large cats {> 4 kg}

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1.60 ml pipette delivers:
Active substance: 320 mg metaflumizone

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

Box of 1 blister card of 3 x 1.60 ml pipettes
Box of 2 blister cards of 3 x 1.60 ml pipettes

5. TARGET SPECIES

For cats over 8 weeks of age.

6. INDICATION(S)

For the treatment and prevention of infestations by fleas.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Do not administer to kittens under 8 weeks of age. Consult your veterinarian before using the veterinary medicinal product on sick or debilitated cats.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

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

Dispose of waste material in accordance with local requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder
Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/064/003 – 1 blister card of 3 pipettes of 1.60 ml
EU/2/06/064/004 – 2 blister cards of 3 pipettes of 1.60 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

FOIL 0.80ml for small cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris S
Spot-on solution

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PFIZER

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

FOIL 1.60 ml for large cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris L
Spot-on solution

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PFIZER

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

for small cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris S
Spot-on solution

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PFIZER

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

160 mg

4. EXPIRY DATE

EXP {month/year}>

5. BATCH NUMBER

LOT {number}

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

for large cats

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris L
Spot-on solution

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PFIZER

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

320 mg

4. EXPIRY DATE

EXP {month/year}>

5. BATCH NUMBER

LOT {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
ProMeris Spot-on for cats

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

Marketing authorisation holder
Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

Manufacturer for the batch release
Wyeth Lederle Italia S.p.A.
18, Via Franco Gorgone
95121 Catania
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris 160 mg Spot-on for small cats
ProMeris 320 mg Spot-on for large cats

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active Substance
Each ml contains 200 mg metaflumizone

Each unit dose (pipette) of ProMeris delivers:

	Volume (ml)	Metaflumizone (mg)
ProMeris for Small Cats (≤ 4 kg)*	0.80	160
ProMeris for Large Cats (> 4 kg)*	1.60	320

***Due to limited space on the packaging, the abbreviations "S" and "L", which represent "small" and "large", respectively, are used on the blister foil and applicator pipettes.**

4. INDICATION(S)

Treatment and prevention of flea infestations (*Ctenocephalides canis* and *C. felis*) in cats. The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

5. CONTRAINDICATIONS

Do not use in kittens under 8 weeks of age.
In sick or debilitated animals use only according to the benefit/risk assessment.

6. ADVERSE REACTIONS*

Hypersalivation may occur if the animal licks the application site immediately after treatment. This is not a sign of intoxication and disappears within minutes without treatment. Correct application will minimise licking of the application site.

The application of the veterinary medicinal product may produce a local, temporary oily appearance and clumping or spiking of the fur at the application site. A dry residue may also be observed. This is normal and will generally resolve within 1 – 4 days after administration. These changes do not affect the safety or efficacy of the veterinary medicinal product. In rare cases, transient irritation may occur at the site of the product application. In very rare cases temporary local hair loss may occur.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

*- Very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- Common (more than 1 but less than 10 animals in 100 animals)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals)
- Rare (more than 1 but less than 10 animals in 10,000 animals)
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

7. TARGET SPECIES

Cats above 8 weeks of age.

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

Dosage:

The recommended minimum dose is 40 mg metaflumizone/kg bodyweight, equivalent to 0.20ml/kg bodyweight. The following table defines the size of pipette to be used according to the weight of the cat.

Weight Of Cat (kg)	Pipette size to be used	Volume (ml)
≤ 4	ProMeris for Small Cats	0.80
> 4	ProMeris for Large Cats	1.60

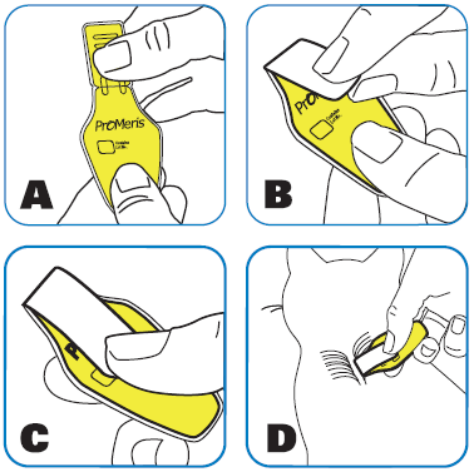
Method of administration:

For cutaneous use only. Spot-on use.

Remove the pipette from the package. Hold the pipette upright, bend the tip of the pipette to break the tip along the scored line. The top of the tip will fold back against the pipette.

Apply the content of the pipette to a single spot on the skin of the cat's neck at the base of the skull. Part the fur on the cat'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 to empty the entire contents.

Do not apply the veterinary medicinal product to the surface of the cat's hair coat.



Treatment schedule:

For optimal control of flea infestation, the veterinary medicinal product can be administered at 4 to 6 week intervals throughout the flea season or the treatment schedule can be based on the local epidemiological situation.

The veterinary medicinal product will prevent flea infestation for up to 6 weeks following a single administration depending on the level of environmental rechallenge.

9. ADVICE ON CORRECT ADMINISTRATION

For use only under the supervision of a veterinary surgeon.

This veterinary medicinal product is for spot-on application only. Do not administer orally or via any other route.

It is important to apply the dose to an area where the animal cannot lick it off. Do not allow animals to groom each other following treatment.

Care should be taken to ensure that the contents of the pipette or the applied dose does not come into contact with the eyes or mouth of the recipient and/or other animals.

For optimum control of flea problems in a multi-pet household, all pets in the household should be treated with a suitable insecticide. In addition, it is recommended to treat the environment with a suitable insecticide.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25 °C.Do not use after the expiry date stated on the carton after "EXP".

12. SPECIAL WARNING(S)

Avoid contact with the eyes of the cat and avoid oral ingestion by the animal.

In sick or debilitated animals, use only according to the benefit/risk assessment.

Can be used during pregnancy and lactation.

No adverse effects were observed in cats aged 8 weeks and older treated 7 times at two-week intervals with 3-5 times the recommended dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid direct contact with skin, eyes or mouth. Wash hands thoroughly after use. In case of accidental spillage onto skin, wash off immediately with soap and water. If the veterinary medicinal product accidentally gets into eyes, flush the eyes thoroughly with water.

Do not smoke, drink or eat while handling the product.

Avoid direct contact with treated animals until the application site is dry.

Children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended to treat the animals during the evening and that recently treated animals are not allowed to sleep with owners, especially children.
The solvent in ProMeris 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. Carefully dispose of used pipettes immediately after use.

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency http://www.ema.europa.eu

15. OTHER INFORMATION

Each strength of the veterinary medicinal product is available in boxes with 1 and in boxes with 2 blister cards of 3 pipettes.

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.

België/Belgique/Belgien
Pfizer Animal Health s.a.,
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Република България
Pfizer Luxembourg SARL
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Česká republika
Pfizer Animal Health
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Pfizer Oy Animal Health
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España
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Pfizer Animal Health
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