ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo 100.5 mg + 100.5 mg Spot-on for small dogs
ProMeris Duo 199.5 mg + 199.5 mg Spot-on for medium sized dogs
ProMeris Duo 499.5 mg + 499.5 mg Spot-on for medium/large sized dogs
ProMeris Duo 799.5 mg + 799.5 mg Spot-on for large dogs
ProMeris Duo 999 mg + 999mg Spot-on for extra large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances
Each ml contains 150 mg metaflumizone and 150 mg amitraz.

Each unit dose (pipette) of ProMeris Duo delivers:

ProMeris Duo Spot-on for Dogs	Volume (ml)	Metaflumizone (mg)	Amitraz (mg)
for Small Dogs (≤ 5 kg)	0.67	100.5	100.5
for Medium Sized Dogs - (5.1 – 10.0 kg)	1.33	199.5	199.5
for Medium/Large Sized Dogs (10.1 – 25.0 kg)	3.33	499.5	499.5
for Large Dogs (25.1 – 40.0 kg)	5.33	799.5	799.5
for Extra Large Dogs (40.1 – 50.0 kg)	6.66	999	999

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

Dogs over 8 weeks of age

4.2 Indications for use, specifying the target species

For the treatment and prevention of infestations by fleas (*Ctenocephalides canis and C. felis*), and ticks (*Ixodes ricinus, Ixodes hexagonus, Rhipicephalus sanguineus, Dermacentor reticulatus and Dermacentor variabilis*), and treatment of demodicosis (caused by *Demodex* spp.) and lice (*Trichodectes canis*) in dogs. 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 puppies under 8 weeks of age.
Do not administer to cats
Do not administer to sick or debilitated dogs or dogs suffering from heat stress.

4.4 Special warnings

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

The veterinary medicinal product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. Dogs should be prevented from accessing streams and rivers for the 24-hour period following treatment. In cases of frequent water exposure the duration of activity may be reduced. In these cases do not treat more frequently than once a fortnight. If the dog requires shampooing, it is better to do so before applying the veterinary medicinal product.

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

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 and to make sure that animals do not lick each other following treatment.

Do not allow puppies to lick the application site of their mothers when it is still wet.

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

Keep out of reach and sight of children. Stored pipettes must be kept in the intact foil package. This product should not be administered by children.

This product contains amitraz, which can lead to adverse neurological effects in humans and especially in children. Children should not have access to used pipettes. Used pipettes should be disposed of immediately.

Amitraz is a monoamine oxidase inhibitor (MOAI); therefore, people taking MOAI-containing medication should take particular care when handling this product.

Avoid direct contact with treated animals until the application site is dry. Children should not be allowed to have contact with treated animals until the application site is dry. Recently treated animals should not be allowed to sleep with the owners, especially children.

The solvent in ProMeris Duo may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.
ProMeris Duo contains components that, on very rare occasions, can cause respiratory irritation in certain people. To minimise the potential for inhalation, it is recommended that the product is applied in open air or in well ventilated rooms.

This product may cause skin sensitisation and allergic reactions in humans. Dermal exposure to the product should therefore be avoided. The use of protective gloves while handling the product is recommended.

If ill effects are noted following exposure to the product, seek immediate medical assistance, and show the product packaging to the physician.

Wash hands thoroughly after use. In case of accidental spillage onto skin, wash off immediately with soap and water.

This product may cause mild eye irritation. If the product accidentally gets into eyes, they should be thoroughly flushed with water.

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

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 hair at the application site. A dry residue may also be observed. This is normal and will generally resolve within a few days after administration, though may persist longer on rare occasions. 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 product application. In very rare cases temporary local hair loss may occur. In very rare cases, pemphigus foliaceous-like cutaneous signs have been reported. If pemphigus-like signs occur, further use of the product should be avoided. These signs are transient and reversible if prompt and appropriate treatment is administered.

*- 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.
Treatment with other products containing amitraz is not recommended whilst the dog is being treated with ProMeris Duo Spot-On for Dogs.

4.9 Amounts to be administered and administration route

Dosage:

The recommended minimum dose is 20 mg/kg bodyweight for each of metaflumizone and amitraz, equivalent to 0.133ml/kg bodyweight. The following table defines the size of pipette to be used according to the weight of the dog.

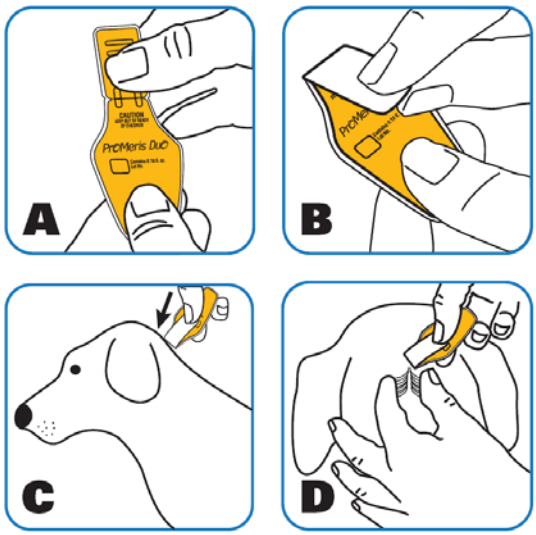
Weight Range of Dog (kg)	Pipette size to be used	Volume (ml)
≤ 5	ProMeris Duo for Small Dogs	0.67
5.1 – 10.0	ProMeris Duo Medium Sized Dogs	1. 33
10.1 – 25.0	ProMeris Duo for Medium/Large Sized Dogs	3. 33
25.1 – 40.0	ProMeris Duo for Large Dogs	5.33
40.1 – 50.0	ProMeris Duo for Extra Large Dogs	6.66

For dogs more than 50 kg, use a combination of two pipettes that most closely matches the body weight.

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.
Part the hair and apply the contents of the pipette to a single spot on the skin of the dog at the base of the skull.
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 dog's hair coat.



Treatment schedule:

For optimal control of flea and/or tick infestation the product should be administered at monthly intervals throughout the flea and/or tick season, or the treatment schedule can be based on the local epidemiological situation. Kills most ticks within 48 hours. For treatment of biting lice a single dose should be sufficient. Most lice are killed within 7 days.

For treatment of demodicosis, the product should be administered at monthly intervals until clinical signs resolve. Where possible, treatment should not be discontinued until skin scrapings are negative on at least two monthly occasions. As demodicosis is a multi-factorial disease, where possible, it is advisable to also treat any underlying disease appropriately.

The veterinary medicinal product will prevent flea infestation for up to 6 weeks and tick infestation for 4 weeks following a single administration.

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

No adverse effects were observed in healthy dogs and puppies aged 8 weeks and older treated 7 times at two-week intervals with 3-5 times the recommended dose. The risk of experiencing adverse effects may however increase when overdosing, so animals should always be treated with the correct pipette size according to body weight.

Known side-effects of amitraz and metabolites are sedation, lethargy, CNS depression, hyperglycaemia, bradycardia and slow, shallow breathing. Most of these signs are due to alpha-2-adreno-receptor agonist effects. Signs are usually transitory and generally resolved without treatment within 24 hours. If symptoms are severe or persist the alpha-2-adreno-receptor antagonist atipamezole hydrochloride may be used at a dose of 0.2 mg/kg bodyweight by intramuscular injection to reverse these side-effects.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ectoparasiticides for topical use, ATC Vet Code QP 53AD51

Metaflumizone is an insecticide belonging to the semicarbazone group of compounds. Metaflumizone is a sodium channel antagonist and disrupts nerve function resulting in paralysis and death of insects.
Amitraz is a formamidine acaricide. It acts at octopamine receptor sites in ectoparasites giving rise to increased nervous activity and death of insects.

Metaflumizone and amitraz are combined in the final formulation to provide a broad spectrum of activity against both fleas and ticks, respectively, 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 at the base of the skull, both metaflumizone and amitraz were rapidly distributed throughout the surface of the skin. Maximum concentrations in the hair were generally reached between 2 to 7 days post treatment and gradually declined through 56 days post treatment. Both components were still measurable in the hair 56 days following treatment.
After topical administration at a single site at the base of the skull, both metaflumizone and amitraz 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

N, N-Diethyl-m-toluamide
1-Methoxy-2-propyl-acetate
Dimethyl sulfoxide
1, 8-Cineole

Gamma-hexalactone

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as package for sale:2 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 over packed 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 0.67 ml pipettes
Box of 1 or 2 blister card of 3 x 1.33 ml pipette
Box of 1 or 2 blister card of 3 x 3.33 ml pipettes
Box of 1 or 2 blister card of 3 x 5.33 ml pipettes
Box of 1 or 2 blister card of 3 x 6.66 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.
The veterinary medicinal product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms. 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/2/06/065/001-010

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 Duo 100.5 mg + 100.5 mg Spot-on for small dogs {≤ to 5 kg}

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.67 ml pipette delivers:

Active substance: 100.5 mg metaflumizone and 100.5 mg amitraz

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

Box of 1 blister card of 3 x 0.67 ml pipettes
Box of 2 blister cards of 3 x 0.67 ml pipettes

5. TARGET SPECIES

For dogs over 8 weeks of age.

6. INDICATION(S)

For the treatment and prevention of infestations by fleas and ticks, and treatment of demodicosis and lice.

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 puppies under 8 weeks of age. Children should not have contact with the product or with animals during treatment. For further information see package leaflet.

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. The veterinary medicinal product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms.

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/2/06/065/001 – 1 blister card of 3 pipettes of 0.67ml
EU/2/06/065/002 – 2 blister cards of 3 pipettes of 0.67ml

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 Duo 199.5 mg + 199.5 mg Spot-on for medium sized dogs {5.1 – 10.0 kg}

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1.33 ml pipette delivers:

Active substance: 199.5 mg metaflumizone and 199.5 mg amitraz

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

Box of 1 blister card of 3 x 1.33 ml pipettes
Box of 2 blister cards of 3 x 1.33 ml pipettes

5. TARGET SPECIES

For dogs over 8 weeks of age.

6. INDICATION(S)

For the treatment and prevention of infestations by fleas and ticks, and treatment of demodicosis and lice.

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 puppies under 8 weeks of age. Children should not have contact with the product or with animals during treatment. For further information see package leaflet.

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. The veterinary medicinal product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms.

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/2/06/065/003 – 1 blister card of 3 pipettes of 1.33ml
EU/2/06/065/004 – 2 blister cards of 3 pipettes of 1.33ml

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 Duo 499.5 mg + 499.5 mg Spot-on for medium/large sized dogs {10.1 – 25.0 kg}

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 3.33 ml pipette delivers:

Active substance: 499.5 mg metaflumizone and 499.5 mg amitraz

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

Box of 1 blister card of 3 x 3.33 ml pipettes
Box of 2 blister cards of 3 x 3.33 ml pipettes

5. TARGET SPECIES

For dogs over 8 weeks of age.

6. INDICATION(S)

For the treatment and prevention of infestations by fleas and ticks, and treatment of demodicosis and lice.

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 puppies under 8 weeks of age. Children should not have contact with the product or with animals during treatment. For further information see package leaflet.

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. The veterinary medicinal product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms.

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/2/06/065/005 – 1 blister card of 3 pipettes of 3.33 ml
EU/2/06/065/006 – 2 blister cards of 3 pipettes of 3.33 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 Duo 799.5 mg + 799.5 mg Spot-on for large dogs {25.1 – 40.0 kg}

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 5.33 ml pipette delivers:

Active substance: 799.5 mg metaflumizone and 799.5 mg amitraz

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

Box of 1 blister card of 3 x 5.33 ml pipettes
Box of 2 blister cards of 3 x 5.33 ml pipettes

5. TARGET SPECIES

For dogs over 8 weeks of age.

6. INDICATION(S)

For the treatment and prevention of infestations by fleas and ticks, and treatment of demodicosis and lice.

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 puppies under 8 weeks of age. Children should not have contact with the product or with animals during treatment. For further information see package leaflet.

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. The veterinary medicinal product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms.

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/2/06/065/007 – 1 blister card of 3 pipettes of 5.33 ml
EU/2/06/065/008 – 2 blister cards of 3 pipettes of 5.33 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 Duo 999 mg + 999 mg Spot-on for extra large dogs {40.1 – 50.0 kg}

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 6.66 ml pipette delivers:

Active substance: 999 mg metaflumizone and 999 mg amitraz

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

Box of 1 blister card of 3 x 6.66 ml pipettes
Box of 2 blister cards of 3 x 6.66 ml pipettes

5. TARGET SPECIES

For dogs over 8 weeks of age.

6. INDICATION(S)

For the treatment and prevention of infestations by fleas and ticks, and treatment of demodicosis and lice.

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 puppies under 8 weeks of age. Children should not have contact with the product or with animals during treatment. For further information see package leaflet.

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. The veterinary medicinal product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms.

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/2/06/065/009 – 1 blister card of 3 pipettes of 6.66 ml
EU/2/06/065/010 – 2 blister cards of 3 pipettes of 6.66 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

FOIL 0.67ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo 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 1.33ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo M
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 3.33ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo M/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 BLISTERS OR STRIPS

FOIL 5.33ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo 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 BLISTERS OR STRIPS

FOIL 6.66ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo XL
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 dogs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo S
Spot-on solution

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PFIZER

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

100.5 mg + 100.5 mg

4. EXPIRY DATE

EXP {month/year}>

5. BATCH NUMBER

LOT {number}

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

for medium sized dogs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo M
Spot-on solution

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PFIZER

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

199.5 mg + 199.5 mg

4. EXPIRY DATE

EXP {month/year}>

5. BATCH NUMBER

LOT {number}

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

for medium/large sized dogs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo M/L
Spot-on solution

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PFIZER

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

499.5 mg + 499.5 mg

4. EXPIRY DATE

EXP {month/year}>

5. BATCH NUMBER

LOT {number}

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

for large dogs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo L
Spot-on solution

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PFIZER

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

799.5 mg + 799.5 mg

4. EXPIRY DATE

EXP {month/year}>

5. BATCH NUMBER

LOT {number}

MINIMUM PARTICULARS TO APPEAR ON PIPETTES

for extra large dogs

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProMeris Duo XL
Spot-on solution

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PFIZER

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

999 mg + 999 mg

4. EXPIRY DATE

EXP {month/year}>

5. BATCH NUMBER

LOT {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

ProMeris Duo 100.5 mg + 100.5 mg Spot-on for small dogs
ProMeris Duo 199.5 mg + 199.5 mg Spot-on for medium sized dogs
ProMeris Duo 499.5 mg + 499.5 mg Spot-on for medium/large sized dogs
ProMeris Duo 799.5 mg + 799.5 mg Spot-on for large dogs
ProMeris Duo 999 mg + 999mg Spot-on for extra large dogs

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 Duo 100.5 mg + 100.5 mg Spot-on for small dogs
ProMeris Duo 199.5 mg + 199.5 mg Spot-on for medium sized dogs
ProMeris Duo 499.5 mg + 499.5 mg Spot-on for medium/large sized dogs
ProMeris Duo 799.5 mg + 799.5 mg Spot-on for large dogs
ProMeris Duo 999 mg + 999mg Spot-on for extra large dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substances
Each ml contains 150 mg metaflumizone and 150 mg amitraz.

Each unit dose (pipette) of ProMeris Duo delivers:

	Volume (ml)	**Metaflumizone (mg)**	**Amitraz (mg)**
ProMeris Duo Spot-on for Small Dogs (≤ 5 kg)*	0.67	100.5	100.5
ProMeris Duo Spot-on for Medium Sized Dogs - (5.1 – 10.0 kg)*	1.33	199.5	199.5
ProMeris Duo Spot-on for Medium/Large Sized Dogs (10.1 – 25.0 kg)*	3.33	499.5	499.5
ProMeris Duo Spot-on for Large Dogs (25.1 – 40.0 kg)*	5.33	799.5	799.5
ProMeris Duo Spot-on for Extra Large Dogs (40.1 – 50.0 kg)*	6.66	999	999

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

4. INDICATION(S)

For the treatment and prevention of infestations by fleas (*Ctenocephalides canis* and *C. felis*) and ticks (*Ixodes ricinus, Ixodes hexagonus, Rhipicephalus sanguineus, Dermacentor reticulates* and *Dermacentor variabilis*), and treatment of demodicosis (caused by *Demodex spp.*) and lice (*Trichodectes canis*) in dogs. The veterinary medicinal product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

5. CONTRAINDICATIONS

Do not administer to puppies under 8 weeks of age.
Do not administer to cats.
Do not administer to sick or debilitated dogs or dogs suffering from heat stress.

6. ADVERSE REACTION*

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 hair at the application site. A dry residue may also be observed. This is normal and will generally resolve within a few days after administration, though may persist longer on rare occasions. 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 product application. In very rare cases temporary local hair loss may occur. In very rare cases, pemphigus foliaceous-like cutaneous signs have been reported. If pemphigus-like signs occur, further use of the product should be avoided. These signs are transient and reversible if prompt and appropriate treatment is administered.
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

For dogs over 8 weeks of age.

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

Dosage:

The recommended minimum dose is 20 mg/kg bodyweight for each of metaflumizone and amitraz, equivalent to 0.133ml/kg bodyweight. The following table defines the size of pipette to be used according to the weight of the dog.

Weight Range of Dog (kg)	Pipette size to be used	Volume (ml)
≤5	**ProMeris Duo for Small Dogs**	0.67
5.1 – 10.0	**ProMeris Duo Medium Sized Dogs**	1. 33
10.1 – 25.0	**ProMeris Duo Spot-on for Medium/Large Sized Dogs**	3. 33
25.1 – 40.0	**ProMeris Duo Spot-on for Large Dogs**	5.33
40.1 – 50.0	**ProMeris Duo Spot-on for Extra Large Dogs**	6.66

For dogs more than 50 kg, use a combination of two pipettes that most closely matches the body weight.

Method of administration:

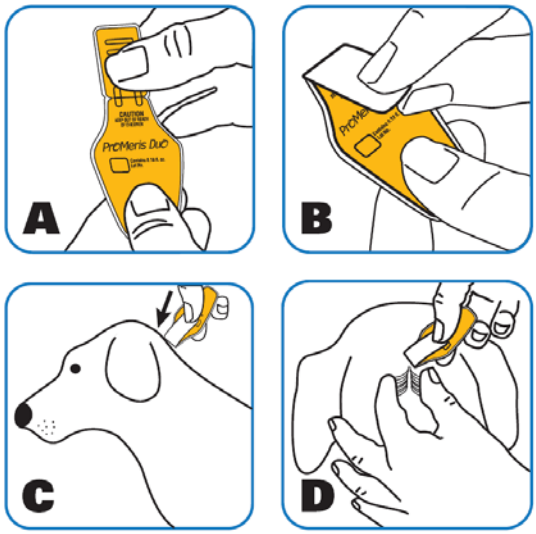
For cutaneous use only. Spot-on use.

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 dog at the base of the skull.

Place the tip of the pipette on the skin and squeeze the pipette to empty the entire contents.

Do not apply the medicine to the surface of the dog's hair coat.



Treatment schedule:

For optimal control of flea and/or tick infestation the veterinary medicinal product should be administered at monthly intervals throughout the flea and/or tick season, or the treatment schedule can

be based on the local epidemiological situation. For treatment of biting lice a single dose should be sufficient. Kills most ticks within 48 hours. Most lice are killed within 7 days.

For treatment of demodicosis, the product should be administered at monthly intervals until clinical signs resolve. Where possible, treatment should not be discontinued until skin scrapings are negative on at least two monthly occasions. As demodicosis is a multi-factorial disease, where possible, it is advisable to also treat any underlying disease appropriately.

The veterinary medicinal product will prevent flea infestation for up to 6 weeks and tick infestation for 4 weeks following a single administration.

9. ADVICE ON CORRECT ADMINISTRATION

For use only under the supervision of a veterinary supervision.

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 and to make sure that animals do not lick each other following treatment.

Do not allow puppies to lick the application site of their mothers when it is still wet.

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.

The veterinary medicinal product remains effective if the animal becomes wet. However, prolonged, intense exposure to water should be avoided. Dogs should be prevented from accessing streams and rivers for the 24-hour period following treatment. In cases of frequent water exposure the duration of activity may be reduced. In these cases do not treat more frequently than once a fortnight. If the dog requires shampooing, it is better to do so before applying the veterinary medicinal product.

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 dog and avoid oral ingestion by the dog.

Can be used during pregnancy and lactation.

Treatment with other products containing amitraz is not recommended whilst the dog is being treated with ProMeris Duo Spot-On for Dogs.

No adverse effects were observed in healthy dogs and puppies aged 8 weeks and older treated 7 times at two-week intervals with 3-5 times the recommended dose. The risk of experiencing adverse effects may however increase when overdosing, so animals should always be treated with the correct pipette size according to body weight.

Known side-effects of amitraz and metabolites are sedation, lethargy, CNS depression, hyperglycaemia, bradycardia and slow, shallow breathing. Most of these signs are due to alpha-2-adreno-receptor agonist effects. Signs are usually transitory and generally resolved without treatment within 24 hours. If symptoms are severe or persist the alpha-2-adreno-receptor antagonist atipamezole hydrochloride may be used at a dose of 0.2 mg/kg bodyweight by intramuscular injection to reverse these side-effects.

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

Stored pipettes must be kept in the intact foil package. This product should not be administered by children.

This product contains amitraz, which can lead to adverse neurological effects in humans and especially in children. Children should not have access to used pipettes. Used pipettes should be disposed of immediately.
Amitraz is a monoamine oxidase inhibitor (MOAI); therefore, people taking MOAI-containing medication should take particular care when handling this product.

Avoid direct contact with treated animals until the application site is dry. Children should not be allowed to have contact with treated animals until the application site is dry. Recently treated animals should not be allowed to sleep with the owners, especially children.

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

ProMeris Duo contains components that, on very rare occasions, can cause respiratory irritation in certain people. To minimise the potential for inhalation, it is recommended that the product is applied in open air or in well ventilated rooms.

This product may cause skin sensitisation and allergic reactions in humans. Dermal exposure to the product should therefore be avoided. The use of protective gloves while handling the product is recommended.

If ill effects are noted following exposure to the product, seek immediate medical assistance, and show the product packaging to the physician.

Wash hands thoroughly after use. In case of accidental spillage onto skin, wash off immediately with soap and water.

This product may cause mild eye irritation. If the product accidentally gets into eyes, they should be thoroughly flushed with water.

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

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.

The veterinary medicinal product should not enter watercourses, as this may be dangerous for fish and other aquatic organisms.

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.,
Tél/Tel.: +32 (0)2 554 62 11

Република България
Pfizer Luxembourg SARL
Тел: + 359 2 970 41 71

Česká republika
Pfizer Animal Health
Tel: +420 283 004 111

Danmark
Pfizer Oy Animal Health
Tlf: +358 (0)9 4300 40

Deutschland
Pfizer GmbH
Tel: +49 30-5500 5501

Eesti
Pfizer Animal Health
Tel: +370 525 14000

Ελλάδα
Pfizer Hellas A.E.
Τηλ.: +30 210 6785800

España
Pfizer S.L.
Tel: +34 91 4909900

France
Pfizer
Tél: +33 (0)1 58 07 46 00

Ireland
Pfizer Healthcare Ireland, trading as:
Pfizer Animal Health
Tel: +353 (0) 1 467 6500

Ìsland
Pfizer Oy Animal Health
Sími: +358 (0)9 4300 40

Italia
Pfizer Italia S.r.l.,
Tel: +39 06 3318 2933

Κύπρος
Pfizer Hellas A.E.
Τηλ.: +30 210 6785800

Luxembourg
Pfizer Animal Health s.a.,
Tél/Tel.: + 32 (0)2 554 62 11

Magyarország
Pfizer Kft.
Tel: +361 488 3695

Malta
Agrimed Limited
Tel: +356 21 465 797

Nederland
Pfizer Animal Health B.V.,
Tel: +31 (0)10 4064 600

Norge
Pfizer Oy Animal Health
Tlf: +358 (0)9 4300 40

Österreich
Pfizer Corporation Austria Ges.m.b.H.
Tel: +43 (0)1 52 11 57 20

Polska
Pfizer Trading Polska Sp. z o.o.
Tel: +48 22 335 61 00

Portugal
Laboratórios Pfizer, Lda.
Tel: +351 21 423 55 00

Romania
Pfizer Romania SRL
Tel: + 0040 21 207 28 00

Slovenija
Pfizer Luxembourg SARL
Tel: +386 (0) 1 52 11 670

Slovenská republika
Pfizer Luxembourg SARL o.z.
Tel: + 421 2 3355 5500

Suomi/Finland
Pfizer Oy Animal Health,
Puh/Tel: +358 (0)9 4300 40

Sverige
Orion Pharma Animal Health
Tlf: +46 (0)8 623 64 40

Latvija
Pfizer Animal Health
Tel: +370 525 14000

Lietuva
Pfizer Animal Health
Tel: +370 525 14000

United Kingdom
Pfizer Ltd
Tel: +44 (0) 1304 616161