

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

qs to 100 ml

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*) 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. It is therefore strongly recommended to treat the animals during the evening and that recently treated animals are not allowed to sleep with owners, especially children.

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)

Known side-effects of amitraz and metabolites, such as sedation, lethargy, CNS depression, hyperglycaemia, bradycardia and slow, shallow breathing may be observed in a small number of animals. 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.

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.

4.7 Use during pregnancy, lactation or lay

Can be used in pregnant and lactating animals.

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:

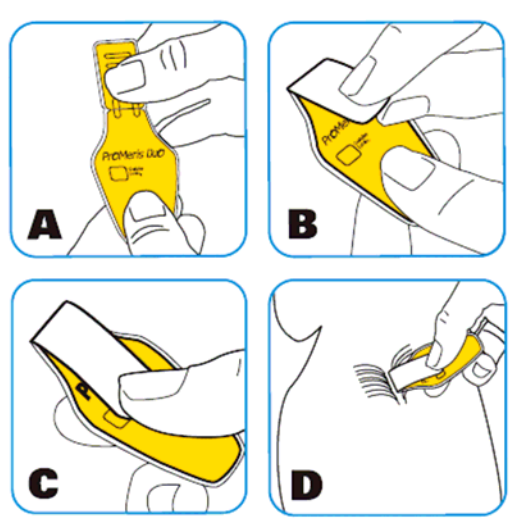
For external use only. Spot-on use.

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 between the shoulder blades.

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.

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

ATC Vet Code QP 53AD51

Pharmacotherapeutic group:

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 between the shoulder blades, 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 between the shoulder blades, 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: 24 months.

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 0.67 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

Fort Dodge Animal Health Holland
C.J. van Houtenlaan 36
1381 CP Weesp,
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/065/001-010

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 December 2007

10 DATE OF REVISION OF THE TEXT

24.07.2007

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (EMA) <http://www.emea.europa.eu>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

ANNEX II

- A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE**
- C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE**
- D. STATEMENT OF THE MRLs**

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Wyeth Lederle Italia S.p.A.
Via Franco Gorgone
95030 Catania
Italy

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary 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. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external 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. Do not administer to pregnant and lactating animals. 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

Fort Dodge Animal Health
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external 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. Do not administer to pregnant and lactating animals. 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

Fort Dodge Animal Health
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external 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. Do not administer to pregnant and lactating animals. 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

Fort Dodge Animal Health
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external 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. Do not administer to pregnant and lactating animals. 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

Fort Dodge Animal Health
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external 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. Do not administer to pregnant and lactating animals. 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

Fort Dodge Animal Health
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

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 SMALL IMMEDIATE PACKAGING UNITS

FOIL 0.67 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Metaflumizone 100.5 mg and amitraz 100.5 mg

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

0.67 ml

4. ROUTE(S) OF ADMINISTRATION

For external use only

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FOIL 1.33 ml

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Metaflumizone 199.5 mg and amitraz 199.5 mg

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

1.33 ml

4. ROUTE(S) OF ADMINISTRATION

For external use only

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FOIL 3.33 ml

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Metaflumizone 499.5 mg and amitraz 499.5 mg

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

3.33 ml

4. ROUTE(S) OF ADMINISTRATION

For external use only

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FOIL 5.33 ml

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Metaflumizone 799.5 mg and amitraz 799.5 mg

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

5.33 ml

4. ROUTE(S) OF ADMINISTRATION

For external use only

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

FOIL 6.66 ml

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. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Metaflumizone 999 mg and amitraz 999 mg

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

6.66 ml

4. ROUTE(S) OF ADMINISTRATION

For external use only

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. 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

2. NAME OF THE MARKETING AUTHORISATION HOLDER

FORT DODGE

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

PrMeris Duo M

2. NAME OF THE MARKETING AUTHORISATION HOLDER

FORT DODGE

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

2. NAME OF THE MARKETING AUTHORISATION HOLDER

FORT DODGE

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

2. NAME OF THE MARKETING AUTHORISATION HOLDER

FORT DODGE

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

2. NAME OF THE MARKETING AUTHORISATION HOLDER

FORT DODGE

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 Spot-on for 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

Fort Dodge Animal Health
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

Manufacturer for the batch release

Wyeth Lederle Italia S.p.A.
18, Via Franco Gorgone
95030 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:

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

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 reticulatus* and *Dermacentor variabilis*) 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.

Do not administer to pregnant and lactating animals.

6. ADVERSE REACTIONS

Known side-effects of amitraz and metabolites, such as sedation, lethargy, CNS depression, hyperglycaemia, bradycardia and slow, shallow breathing may be observed in a small number of animals. Most of these signs are due to alpha-2-adreno-receptor agonist effects. Signs are usually transitory and generally resolve 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.

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.

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

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 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:

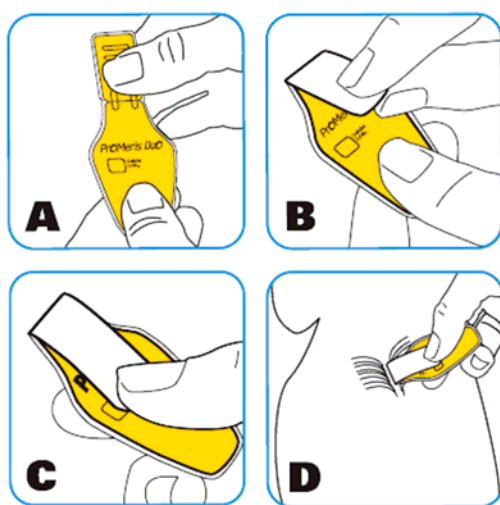
For external use only. Spot-on use.

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 between the shoulder blades.

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.

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 surgeon.

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

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)

Keep out of the 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. It is therefore strongly recommended to treat the animals during the evening and that recently treated animals are not allowed to sleep with owners, especially children.

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

24.07.2007

Detailed information on this product is available on the website of the European Medicines Agency (EMA) <http://www.emea.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.

(Local representatives)

België/Belgique/Belgien
Fort Dodge Veterinär GmbH
Duitsland/Allemagne/Deutschland
Tel/Tél: + 32 (0)2 713 1422

Luxemburg/Luxembourg
Fort Dodge Veterinär GmbH
Allemagne/Deutschland
Tel: + 32 2 713 1422

Република България
”СаниКо БЪЛГАРИЯ” ООД
Тел: + 359 28514413

Magyarország
Cymedica Hungary Kft.
Tel.: + 36 305 652 187

Česká republika
Cymedica spol s.r.o.
Tel: + 420 311 545 011

Malta
Fort Dodge Animal Health
The Netherlands
Tel: + 31 35 699 3365

Danmark
ScanVet Animal Health A/S
Tlf: + 45 48 48 43 17

Nederland
Fort Dodge Veterinär GmbH
Duitsland
Tel: + 31 (0)20 346 9360

Deutschland
Fort Dodge Veterinär GmbH
Tel: + 49 (0)2405 454 100

Norge
ScanVet informasjonskontor
Tlf: +47 22 76 72 50

Eesti
Linax Agro Veterinarijos Centras Ltd.
Leedu
Tel: + 370 45 507 400

Österreich
Fort Dodge Veterinär
Tel: + 43 (0)6245 7065316

Ελλάδα
Provet S.A.
Τηλ: + 30 21 0 55 73803-5

Polska
ScanVet Poland Sp. z .o. o.
Tel.: +48 61 426 49 20

España

Fort Dodge Veterinaria S.A.
Tel: + 34 91 598 1336

Portugal

Fort Dodge Veterinaria S.A.
Espanha
Tel: + 34 91 598 1336

France

Fort Dodge Santé Animale
Tel: + 33 (0)2 47 74 89 89

România

Torox srl
Tel: + 40212509306

Ireland

Fort Dodge Animal Health Ltd.
UK
Tel: + 44 1489 781 711

Slovenija

Vet4vet d.o.o.
Tel: +386 1 2800672

Ísland

Vistor hf.
Sími: + 354 535 7000

Slovenská republika

Cymedica spol s.r.o.
Česká republika
Tel: + 420 311 545 011

Italia

Fort Dodge Veterinaria S.p.A.
Tel.: + 39 051 421 53 11

Suomi/Finland

ScanVet Eläinlääkkeet Oy
Puh/Tel: + 358 (0)3 630 3100

Κύπρος

Premier Shukuroglou Ltd.
Τηλ: + 357 22815353

Sverige

Ceva Vetpharma AB
Tel: + 46 (0)46 12 81 00

Latvija

Linās Agro Veterinārijos Centras Ltd.
Lietuva
Tel: + 370 45 507 400

United Kingdom

Fort Dodge Animal Health Ltd.
Tel: + 44 (0)1489 781 711

Lietuva

Linās Agro Veterinārijos Centras Ltd.
Tel: + 370 45 507 400