

80490-2

10/31/2007

10f28



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

October 31, 2007

Mr. Bosco Wang, Ph.D.
Associate Regulatory Affairs Fellow
FORT DODGE ANIMAL HEALTH
P.O. Box 5366
Princeton, NJ 08543-5366

Subject: Label Notification

Dear Dr. Wang:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 9/6/07 for **EPA Registration 80490-2**. The Registration Division (RD) has conducted a review of this request for applicability under PRN 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact me directly at 703-305-6249 or Sherada Hobgood of my staff at 703-308-8893.

Sincerely,

A handwritten signature consisting of the letters "L" and "S" in a stylized, cursive font.

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

20f28

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 80490 / 80490-2	2. EPA Product Manager John Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Fort Dodge Animal Health / ProMeris for Dogs	PM# 7	
5. Name and Address of Applicant (Include ZIP Code) Fort Dodge Animal Health PO Box 5366 Princeton, NJ 08543-5366 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>80490-2</u> Product Name <u>ProMeris for Dogs</u>	

Section - II

NOTIFICATION

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated <u>OCT 31 2007</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of "Direction for Use" change per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of the product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of (continue to the next page)

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. 2 sizes	No. per container 6
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 0.67; 1.33; 3.33; 5.33 & 6.66 mL/unit	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Bosco Wang, Ph.D.	Title Associate Regulatory Affairs Fellow	Telephone No. (Include Area Code) (732) 631-5312
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete... I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Associate Regulatory Affairs Fellow	
4. Typed Name Bosco Wang, Ph.D.	5. Date September 6, 2007	

FORT DODGE ANIMAL HEALTH

DIVISION OF WYETH

September 6, 2007

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

10/31

ATTN: Mr. John Hebert (PM 7)

SUBJECT: Notification of Change of "Direction of Use"
RE: ProMeris for Dogs (EPA Registration No. 80490-2)

Dear Mr. Hebert:

The registration of "ProMeris for dogs" was conditionally approved by EPA on August 10, 2007. In the Notice of Pesticide Registration, EPA requested the treatment interval statement "DO NOT APPLY MORE THAN ONCE A MONTH" be added to the container labels (comment item #2-g). Fort Dodge Animal Health (FDAH) incorporated the statement, "DO NOT APPLY MORE THAN ONCE MONTHLY", in the final printed product container labels which were submitted to EPA on August 14, 2007. Both statements convey the same meaning; FDAH notifies EPA of the carton label variation in this correspondence per PR Notice 98-10. No other changes have been made to these labels.

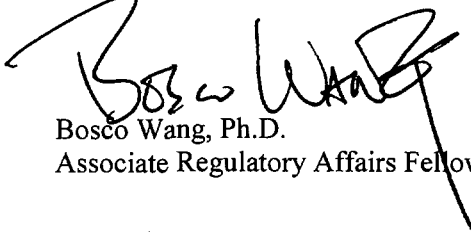
Section II-M-3-(1) of the PR Notice 98-10 states "the application method results in exposure no greater than exposure from the currently registered method(s)". Section II-M-3-(2) of the PR Notice 98-10 further states "the new application method results in no change in dosage, concentration, timing or frequency of application of the product". Therefore, the carton label variation mentioned above fulfills the requirements for Labeling Notifications as described in PR Notice 98-10.

It is FDAH's understanding per PR Notice 98-10 Section VI-A-3-c, the referenced non-antimicrobial product modified by this notification can be distributed and sold once EPA receives this notification.

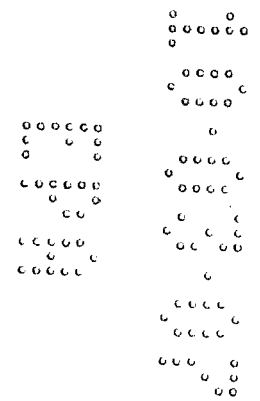
The completed Application for Registration (Form 8570-1) is provided in **Attachment 1** per PR Notice 98-10 Section VI-A-1. One set of the final printed labels including those "with the changes clearly marked so that they can be photocopied" are included in **Attachment 2** per PR Notice 98-10 Section IV-A-4. Please note these labels were also provided to EPA on August 14, 2007.

Please do not hesitate to contact me if any questions arise. I can be reached by phone: 732-631-5812; fax: 732-631-5815; and email: wangb@pt.fdah.com. Thank you very much.

Sincerely,



Bosco Wang, Ph.D.
Associate Regulatory Affairs Fellow



5028



FORT DODGE ANIMAL HEALTH
DIVISION OF WYETH

Attachment 2

NOTIFICATION
OCT 31 2007

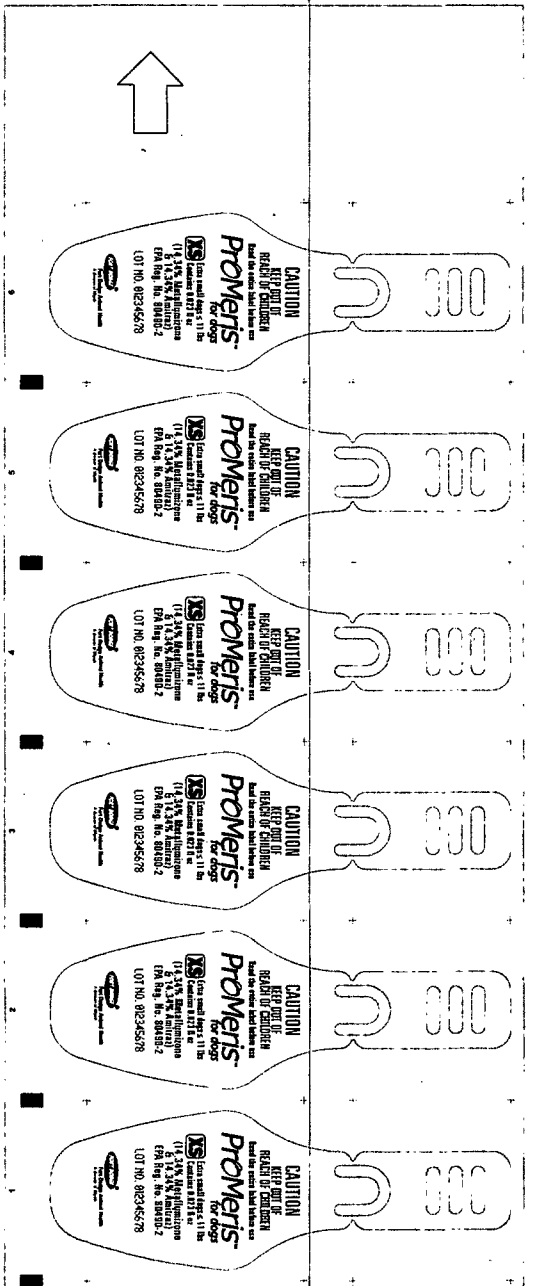
Final Printed Labels

These labels are identical to those previously submitted to EPA on August 14, 2007. Variations in carton labels are presented in pages 13-22 of this attachment. For better illustration, variations are marked with *< >.*

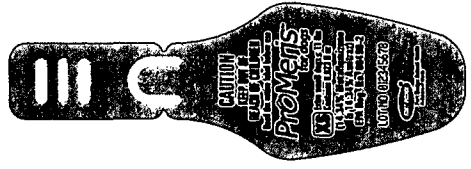
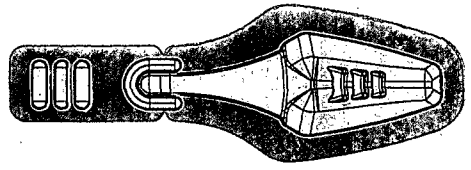
60278

NOTIFICATION

DEC 14 2007



23175 mm

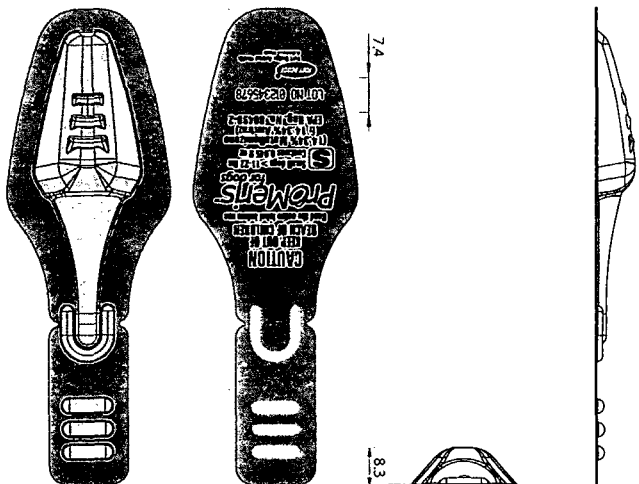


7.7

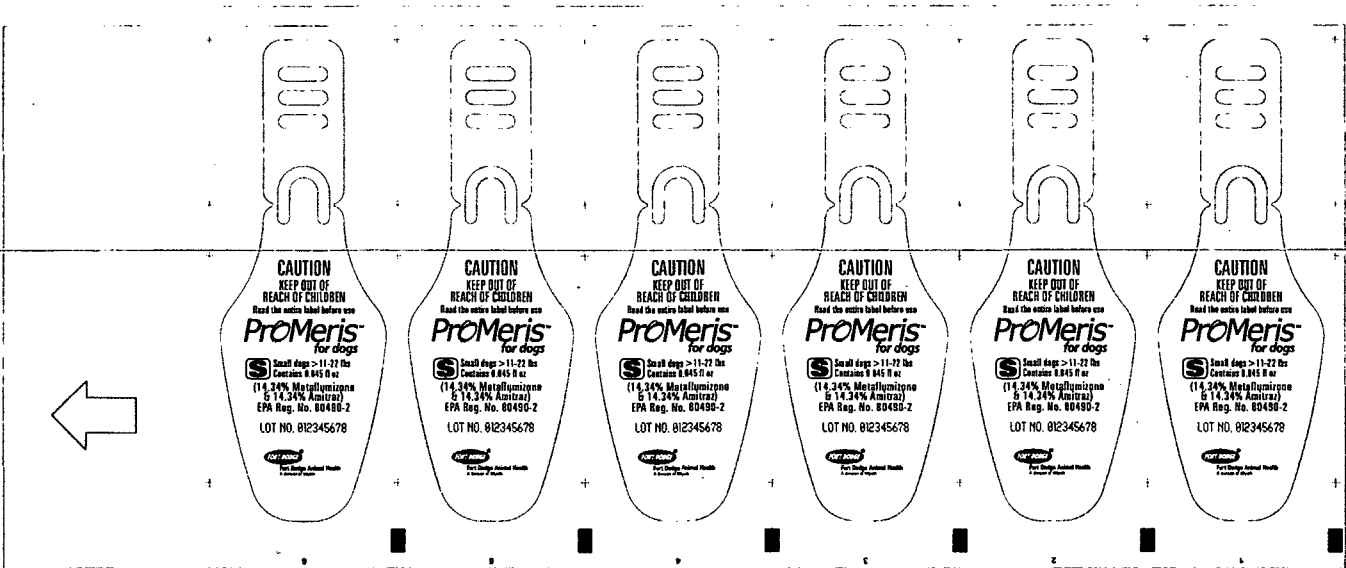
6.5

A0010-00_Dog XS-USA

87301

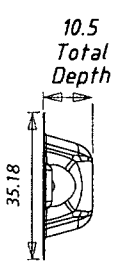
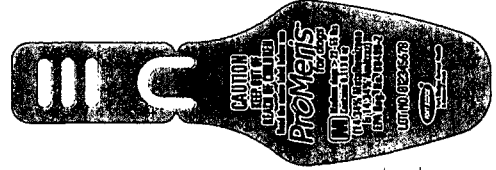
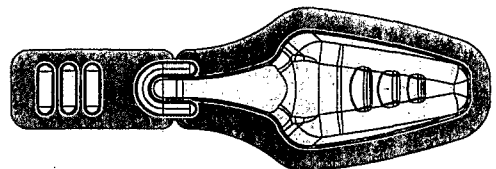
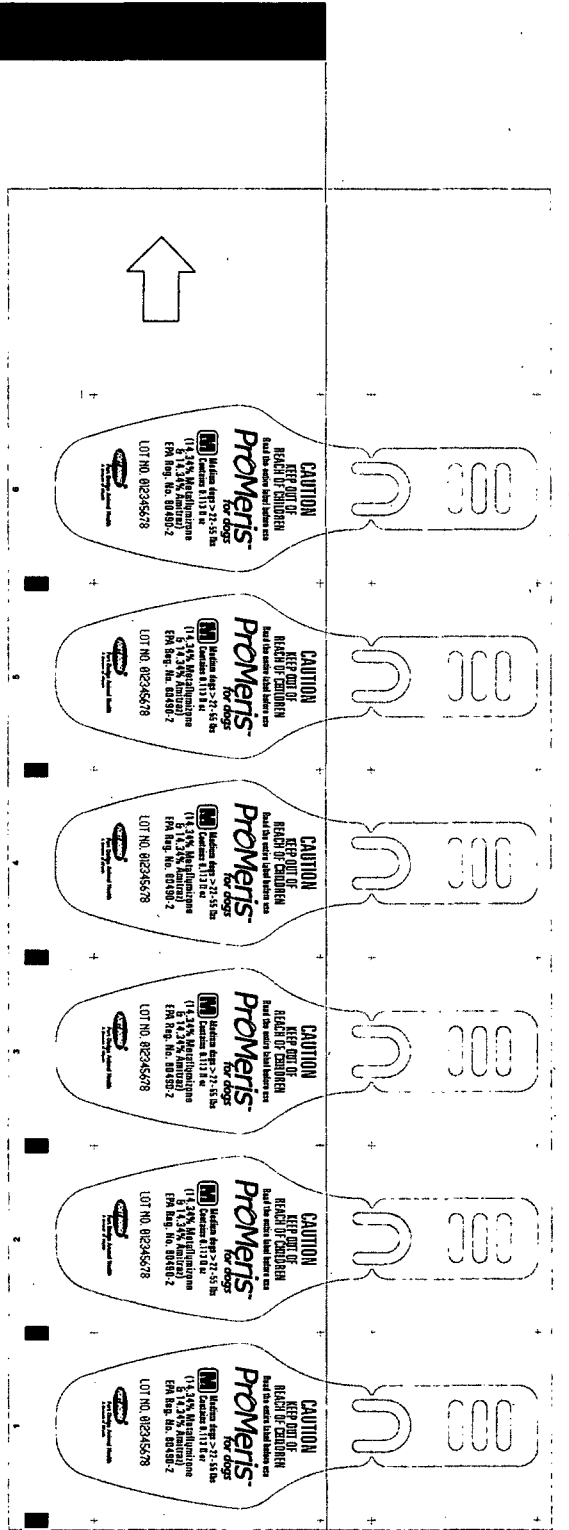


237,76 mm



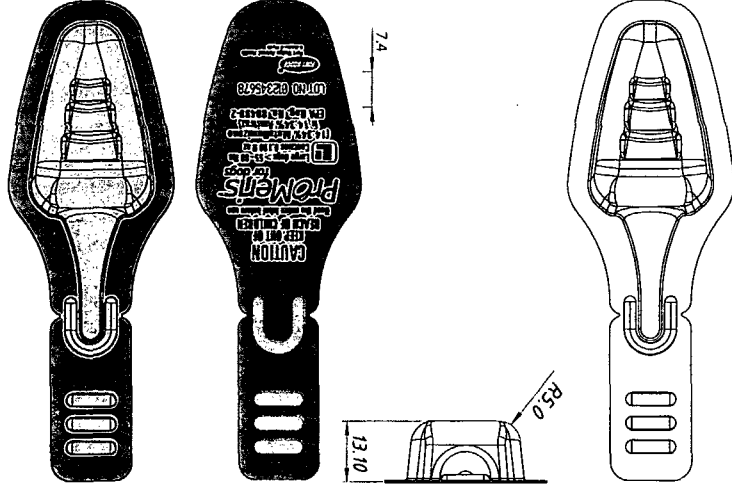
A0008-02_Cat S -USA

80928

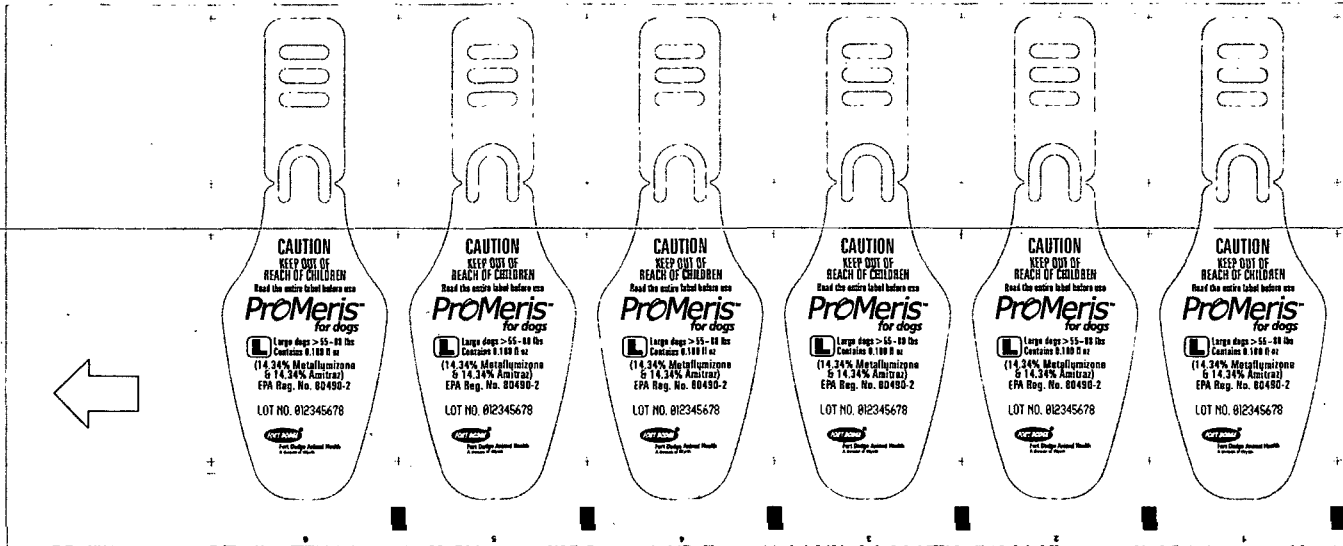


A0012-00_Dog M-USA

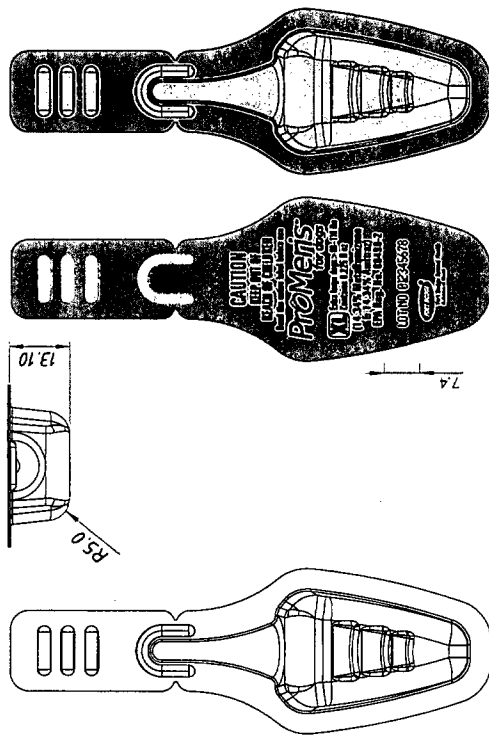
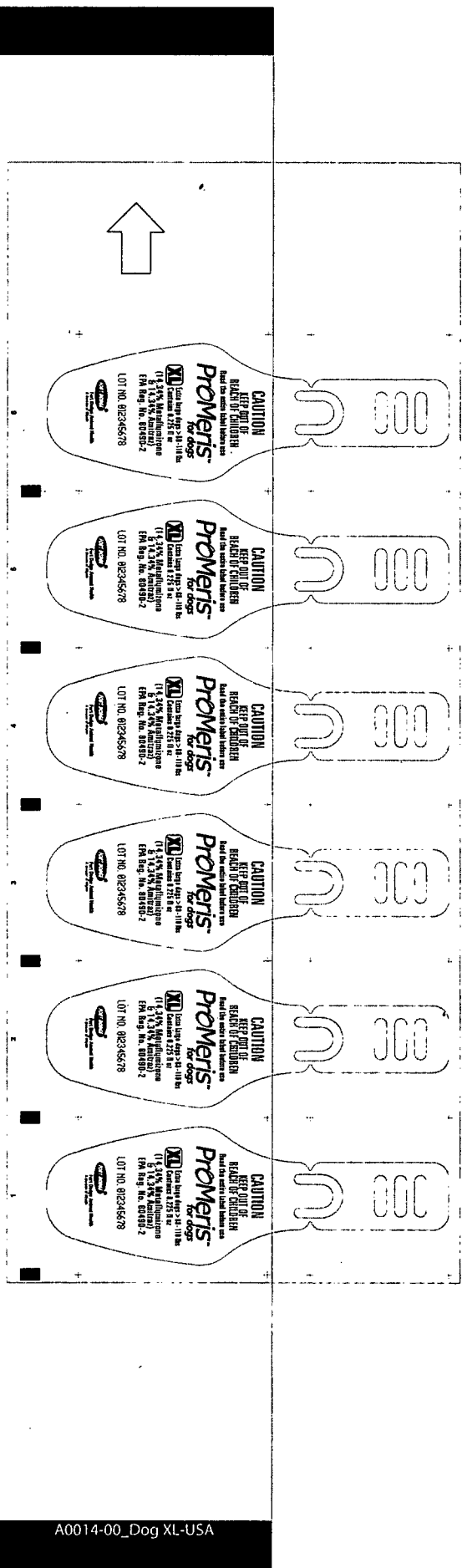
90828



237.75 mm



A0013-00_Dog L-USA



Foil Advance = 2x 130.5 = 261mm

CAUTION
KEEP OUT OF REACH OF CHILDREN
Do not remove applicator until ready to use

ProMeris[®]
for dogs

LOT NO. 012345678

SX

Extra small dogs ≤ 11 lbs
Contains 0.023 fl oz
(14.34% Metololamine
514.34% Amitraz)

EPA Reg. No. 80499-2

PORT DODGE
Fort Dodge Animal Health
A Division of Wyeth

CAUTION
KEEP OUT OF REACH OF CHILDREN
Do not remove applicator until ready to use

ProMeris[®]
for dogs

LOT NO. 012345678

SX

Extra small dogs ≤ 11 lbs
Contains 0.023 fl oz
(14.34% Metololamine
514.34% Amitraz)

EPA Reg. No. 80499-2

PORT DODGE
Fort Dodge Animal Health
A Division of Wyeth

CAUTION
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ProMeris[®]
for dogs

LOT NO. 012345678

SX

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514.34% Amitraz)

EPA Reg. No. 80499-2

PORT DODGE
Fort Dodge Animal Health
A Division of Wyeth

CAUTION
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ProMeris[®]
for dogs

LOT NO. 012345678

SX

Extra small dogs ≤ 11 lbs
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514.34% Amitraz)

EPA Reg. No. 80499-2

PORT DODGE
Fort Dodge Animal Health
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PORT DODGE
Fort Dodge Animal Health
A Division of Wyeth

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Fort Dodge Animal Health
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for dogs

LOT NO. 012345678

SX

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514.34% Amitraz)

EPA Reg. No. 80499-2

PORT DODGE
Fort Dodge Animal Health
A Division of Wyeth

B0059-0 DOG XS_USA

Foil Advance = 2x 130.5 = 261mm



B0060-0 DOG_S_USA



B0061-0 DOG M_USA

Foil Advance = 2x 130.5 = 261mm

CAUTION
KEEP OUT OF REACH OF CHILDREN
Do not remove applicator until ready to use

ProMeris
for dogs

LOT NO. 012345678

Large dogs > 55-88 lbs
Contains 0.180 fl oz
(14.34% Metamizone
514.34% Amitraz)
EPA Reg. No. 80498-2

Fort Dodge Animal Health
A division of Wyeth

CAUTION
KEEP OUT OF REACH OF CHILDREN
Do not remove applicator until ready to use

ProMeris
for dogs

LOT NO. 012345678

Large dogs > 55-88 lbs
Contains 0.180 fl oz
(14.34% Metamizone
514.34% Amitraz)
EPA Reg. No. 80498-2

Fort Dodge Animal Health
A division of Wyeth

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ProMeris
for dogs

LOT NO. 012345678

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(14.34% Metamizone
514.34% Amitraz)
EPA Reg. No. 80498-2

Fort Dodge Animal Health
A division of Wyeth

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ProMeris
for dogs

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514.34% Amitraz)
EPA Reg. No. 80498-2

Fort Dodge Animal Health
A division of Wyeth

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514.34% Amitraz)
EPA Reg. No. 80498-2

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A division of Wyeth

CAUTION
KEEP OUT OF REACH OF CHILDREN
Do not remove applicator until ready to use

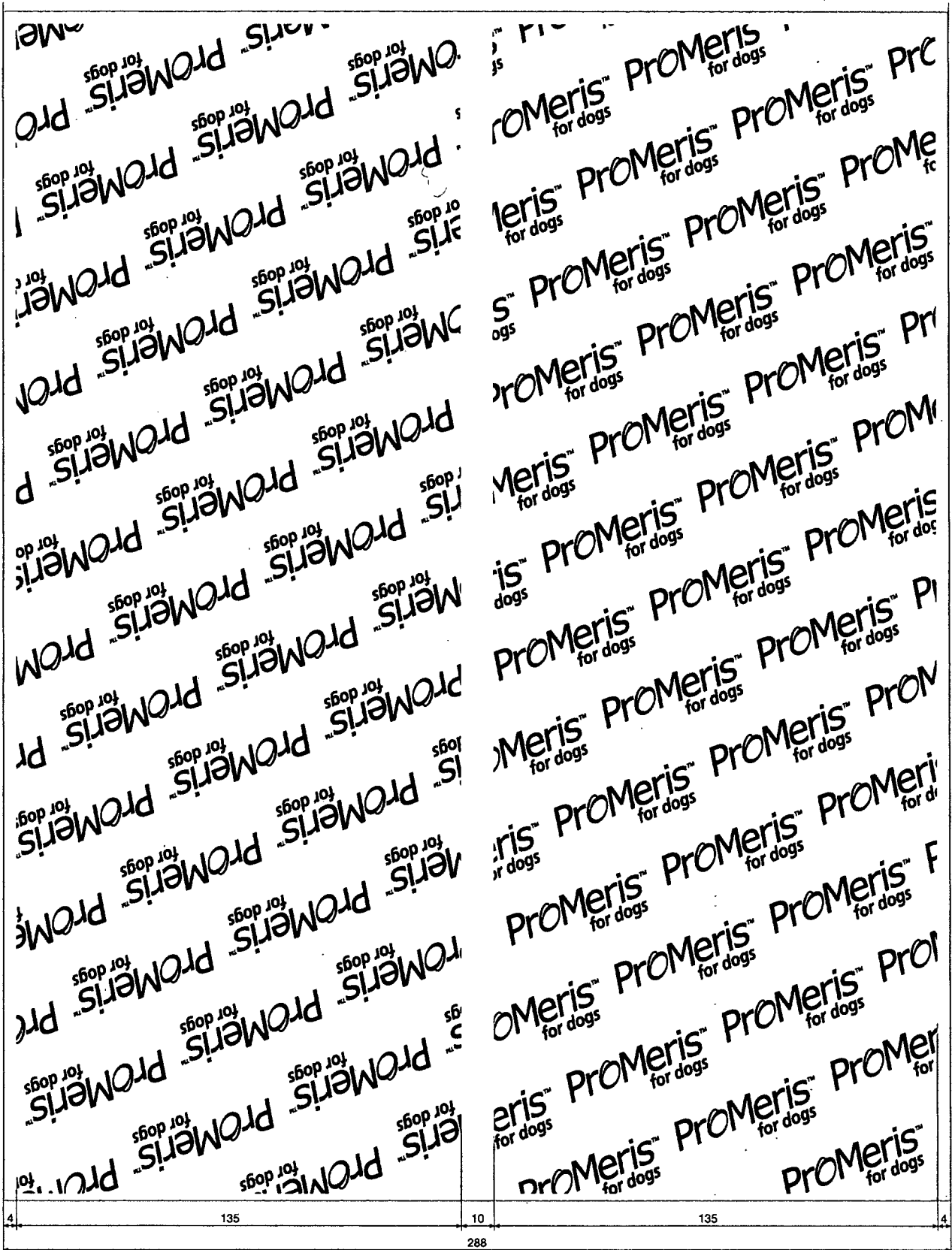
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for dogs

LOT NO. 012345678

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514.34% Amitraz)
EPA Reg. No. 80498-2

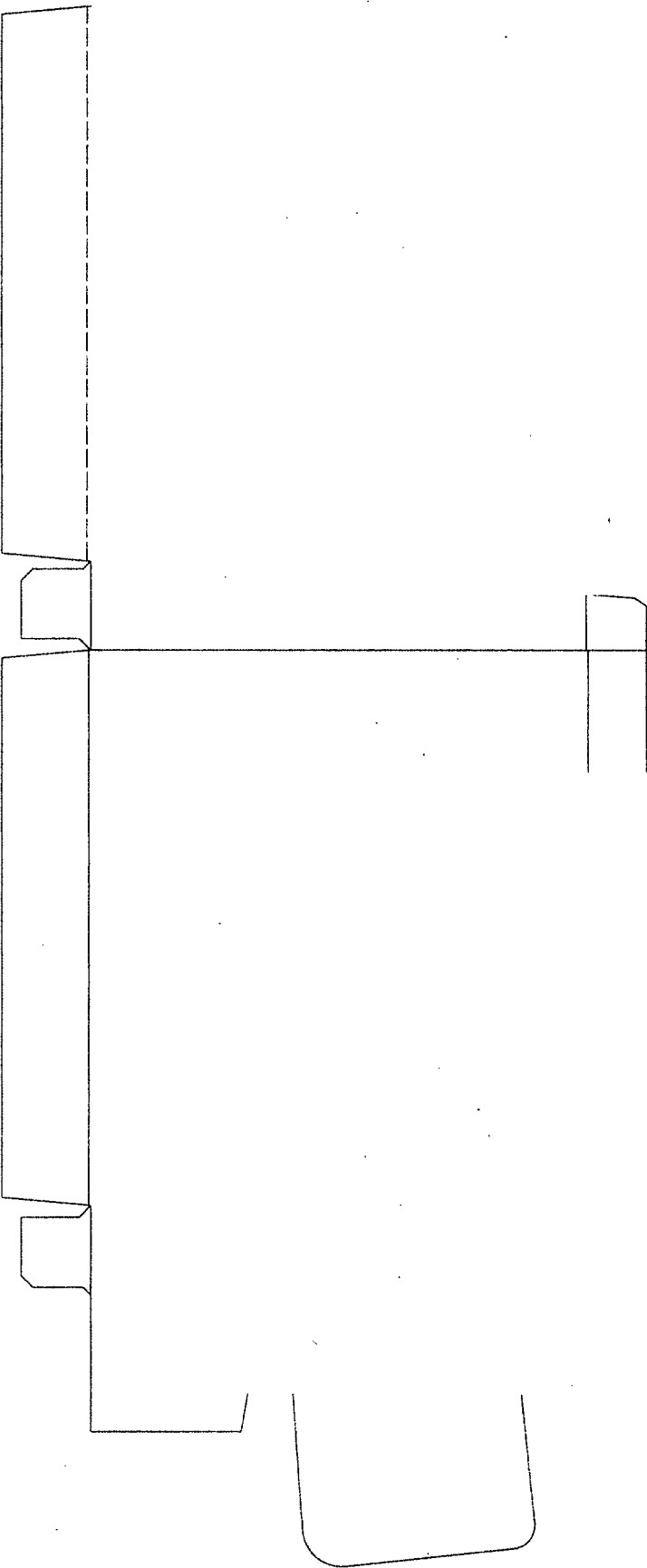
Fort Dodge Animal Health
A division of Wyeth

B0062-0 DOG L_USA




288
Rollenbreite
web width

Maße in mm
measurements in mm



Promeris™ for dogs Consumer Hotline
at 1-888-800MENS (1-888-776-5379)



 Pfizer
The World's Most Innovative
Pharmaceutical Company

18 of 28

3 pack

ProMeris™
for dogs

Single spot application for control of fleas and ticks on dogs 6 weeks of age and older

SX

For dogs 11 pounds and under (≤ 11 lbs)

CAUTION: KEEP OUT OF REACH OF CHILDREN

FOR DOGS 11 POUNDS AND UNDER (≤ 11 LBS)

Net Content: 3 applicators of 0.023 fl oz each

Fort Dodge Animal Health
P.O. Box 25945
Overland Park, KS 66225
MADE IN ITALY



ProMeris™
for dogs

For dogs 11 pounds and under (≤ 11 lbs)

SX

3 pack

Single spot application for control of fleas and ticks on dogs 6 weeks of age and older

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. See inside pamphlet for label information and directions for use. Read the entire label, directions for use and "How to Apply" instructions before using the product each time. For use on dogs only.

For control of fleas (*Ctenocephalides* sp.) and ticks, apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry. Avoid allowing the product to come in contact with your skin. Place empty applicator in trash. Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

For more information, contact your veterinarian or call the ProMeris™ for dogs Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

Fort Dodge Animal Health
P.O. Box 25945
Overland Park, KS 66225
MADE IN ITALY

Fort Dodge
Fort Dodge Animal Health, a division of Wyeth. All rights reserved.

DO NOT USE ON CATS

860028-00 (1/08/07)

8 6 2 0 0 2 6

ProMeris™
for dogs

For dogs 11 pounds and under (≤ 11 lbs)

SX

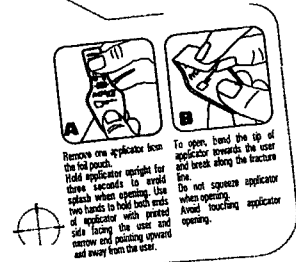
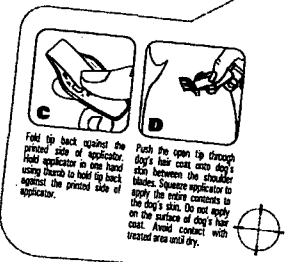
Calendar Reminder

Apply the first reminder sticker to your calendar on the first day you use your dog with ProMeris™ for dogs. Reminders apply all the remaining stickers to your calendar at one-month intervals for each treatment by writing the dates of each treatment in the spaces provided. Do not apply more than once a month.

Date of first treatment: _____
Date of last treatment: _____
Date of last treatment: _____

Lot No. 1051 001 001

8 714015 005289



19028

9 pack

ProMeris™
for dogs

Single spot application for control of fleas and ticks on dogs 6 weeks of age and older.

XS
For dogs 11 pounds and under (≤ 11 lbs)

CAUTION KEEP OUT OF REACH OF CHILDREN

Fort Dodge Animal Health
Overland Park, KS 66225
1-888-PROMERIS (1-888-776-6374)



ProMeris™
for dogs

XS
For dogs 11 pounds and under (≤ 11 lbs)

ProMeris™
for dogs

XS
For dogs 11 pounds and under (≤ 11 lbs)

6 pack

Single spot application for control of fleas and ticks on dogs 6 weeks of age and older.

Directions for Use:
Place empty applicator in trash. Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

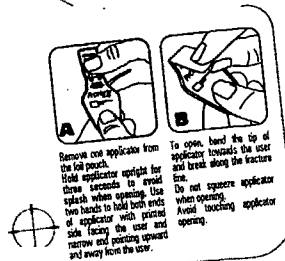
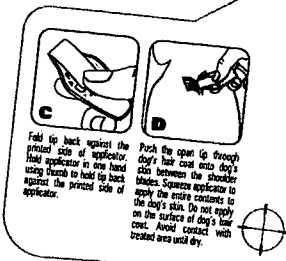
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Fort Dodge Animal Health
P.O. Box 25945
Overland Park, KS 66225
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MADE IN ITALY

DO NOT USE ON CATS

8820032-00
1308807

8 6 2 0 0 3 2



ProMeris™ for dogs

ProMeris™
for dogs

Calendar Reminder

Date of first treatment	Date of last treatment	Date of first treatment	Date of last treatment	Date of first treatment	Date of last treatment

Apply the flea reminder stickers to your calendar on the first day you treat your dog with ProMeris™ for dogs. Immediately apply all the remaining stickers to your calendar at one-month intervals. Check the calendar frequently to ensure the date of each treatment. The stickers provided do not apply more than once a month.

8 714015 005302

Lot No.

200828

3 pack

PROMERIS
for dogs

CAUTION
KEEP OUT OF REACH OF CHILDREN
This product contains chemicals which are known to be hazardous to humans. Use only as directed. Do not use on cats.

Net Content:
3 applicators of 0.045 fl oz each

For dogs over 11 pounds and up to 22 pounds (>11-22 lbs)

Single spot application for control of fleas and ticks on dogs 6 weeks of age and older

Directions for Use:
To use this product in a manner inconsistent with the labeling, see inside pamphlet for label information and directions for use. Read the entire label, directions for use and "How to Apply" instructions before using the product each time. For use on dogs only.

For control of fleas (Ctenocephalides sp.) and ticks, apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry. Avoid allowing the product to come in contact with your skin.

Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

For more information, contact your veterinarian or call the ProMeris™ for dogs Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

Fort Dodge Animal Health
P.O. Box 25945
Overland Park, KS 66225
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MADE IN ITALY



For dogs over 11 pounds and up to 22 pounds (>11-22 lbs)

ProMeris™ for dogs

Single spot application for control of fleas and ticks on dogs 6 weeks of age and older

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To use this product in a manner inconsistent with the labeling, see inside pamphlet for label information and directions for use. Read the entire label, directions for use and "How to Apply" instructions before using the product each time. For use on dogs only.

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Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

For more information, contact your veterinarian or call the ProMeris™ for dogs Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

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Directions for Use:
To use this product in a manner inconsistent with the labeling, see inside pamphlet for label information and directions for use. Read the entire label, directions for use and "How to Apply" instructions before using the product each time. For use on dogs only.

For control of fleas (Ctenocephalides sp.) and ticks, apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry. Avoid allowing the product to come in contact with your skin.

Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

For more information, contact your veterinarian or call the ProMeris™ for dogs Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

Fort Dodge Animal Health
P.O. Box 25945
Overland Park, KS 66225
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MADE IN ITALY

For dogs over 11 pounds and up to 22 pounds (>11-22 lbs)

ProMeris™ for dogs

Single spot application for control of fleas and ticks on dogs 6 weeks of age and older

Directions for Use:
To use this product in a manner inconsistent with the labeling, see inside pamphlet for label information and directions for use. Read the entire label, directions for use and "How to Apply" instructions before using the product each time. For use on dogs only.

For control of fleas (Ctenocephalides sp.) and ticks, apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry. Avoid allowing the product to come in contact with your skin.

Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

For more information, contact your veterinarian or call the ProMeris™ for dogs Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

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P.O. Box 25945
Overland Park, KS 66225
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MADE IN ITALY

For dogs over 11 pounds and up to 22 pounds (>11-22 lbs)

ProMeris™ for dogs

Calendar Reminder

Apply the first reminder sticker to your calendar on the first day you treat your dog with ProMeris™ for dogs. Immediately apply all the remaining stickers to your calendar at 30-day intervals thereafter. Do not treat more than once a month. Do not apply more than once a month.

Date of first treatment: _____
Date of last treatment: _____
Date of next treatment: _____

Lot No. _____

8 714015 005166

2/08/28



ProMeris for dogs

For dogs over 11 pounds and up to 22 pounds (>11-22 lbs)



ProMeris for dogs

For dogs over 11 pounds and up to 22 pounds (>11-22 lbs)



Single spot application for control of fleas (and ticks on dogs 8 weeks of age and older)

ETA Reg. No. 60459-3 EPA Est. No. 61052-71A-001

Net Contents: 6 applicators of 0.048 fl oz each

6 pack

DIRECTIONS FOR USE:
 It is a violation of Federal law to use this product in a manner inconsistent with its labeling. See inside pamphlet for label information and directions for use. Read the entire label directions for use and "How to Apply" instructions before using the product each time. Apply instructions before using the product each time. For use on dogs only.

For control of fleas (*Ctenocephalides* sp.) and ticks, apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry. Avoid allowing the product to come in contact with your skin.

Place empty applicator in trash. Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

For more information, contact your veterinarian or call the ProMeris™ for dogs Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

Fort Dodge Animal Health
 P.O. Box 26945 St. Paul
 Overland Park, KS 66225
 Fort Dodge
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 MADE IN ITALY

DO NOT USE ON CATS

8820033-00
 1348007



8 6 2 0 0 3 3



C Fold tip back against the printed side of applicator. Hold applicator in one hand using thumb to hold tip back against the printed side of applicator.



D Push the open lip through dog's hair coat onto dog's skin, between the shoulder blades. Squeeze applicator to apply the entire contents to the dog's skin. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry.



A Remove one applicator from the foil pouch. Hold applicator upright for three seconds to equalize contents. Use thumb to hold both ends of applicator with printed side facing the user and remove and popping upward and away from the user.



B To open, bend the tip of applicator towards the user and break along the fracture line. Do not squeeze applicator when opening. Avoid touching applicator opening.

ProMeris for dogs

Calendar Reminder

Date of first treatment	Date of last treatment	Date of last treatment	Date of last treatment	Date of last treatment	Date of last treatment

Apply the first reminder sticker to your calendar on the first day you treat your dog with ProMeris for dogs. Immediately apply all the remaining stickers to your calendar at one-month intervals. For each treatment, by writing the date of each treatment in the spaces provided. Do not apply more than once a month.



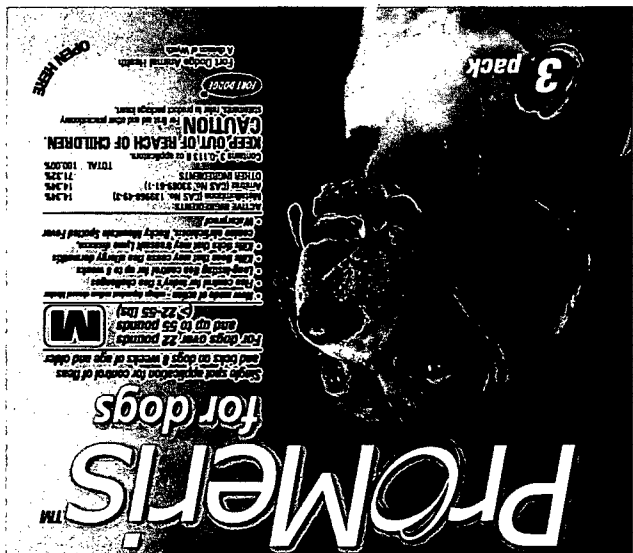
8 714015 005180

Lot No.

1028200000



870727



ProMeris
for dogs

For dogs over 22 pounds
and up to 55 pounds
(> 22-55 lbs)

M

ProMeris
for dogs

For dogs over 22 pounds
and up to 55 pounds
(> 22-55 lbs)

M

3 pack

Single spot application for
control of fleas and ticks on
dogs 8 weeks of age and older.

EPA Reg. No. 90490-2
EPA Est. No. 81052-17A-001

Net Contents:
3 applicators of 0.113 fl. oz each

For dogs over 22 pounds
and up to 55 pounds
(> 22-55 lbs)

ProMeris
for dogs

Fort Dodge intends this product to be sold only by veterinarians and used in established veterinarian/client/patient relationships.

Fort Dodge may institute appropriate legal action if this product is sold by persons outside this veterinarian/client/patient relationship.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. See inside pamphlet for label information and directions for use. Read the entire label, directions for use and "How to Apply" instructions before using the product each time. For use on dogs only.

For control of fleas (*Ctenocephalides* sp.) and ticks, apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry. Avoid allowing the product to come in contact with your skin.

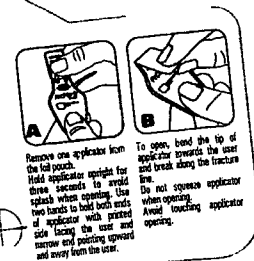
Place empty applicator in trash. Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

For more information, contact your veterinarian or call the ProMeris™ for dogs Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

Fort Dodge Animal Health
P.O. Box 25945
Overland Park, KS 66225
MADE IN ITALY

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DO NOT USE ON CATS



ProMeris
for dogs

Calendar Reminder

Date of first treatment: _____
Date of next treatment: _____
Date of next treatment: _____

Apply the first reminder sticker to your calendar on the first day your dog was treated with ProMeris for dogs. Remind yourself of the remaining stickers on your calendar to schedule future treatments. Do not apply more than once a month.

Lot No. _____

823028

9 pack

ProMeris[®]
for dogs

CAUTION
KEEP OUT OF REACH OF CHILDREN
See back panel for complete instructions.
Do not use on cats.
Do not use on dogs under 22 pounds.
Do not use on dogs over 55 pounds.
Do not use on dogs with open wounds or skin irritation.
Do not use on dogs with known hypersensitivity to the active ingredients.
Do not use on dogs with known hypersensitivity to the inactive ingredients.
Do not use on dogs with known hypersensitivity to the product.
Do not use on dogs with known hypersensitivity to the brand.
Do not use on dogs with known hypersensitivity to the manufacturer.
Do not use on dogs with known hypersensitivity to the distributor.
Do not use on dogs with known hypersensitivity to the retailer.
Do not use on dogs with known hypersensitivity to the wholesaler.
Do not use on dogs with known hypersensitivity to the importer.
Do not use on dogs with known hypersensitivity to the exporter.
Do not use on dogs with known hypersensitivity to the manufacturer's representative.
Do not use on dogs with known hypersensitivity to the manufacturer's agent.
Do not use on dogs with known hypersensitivity to the manufacturer's distributor.
Do not use on dogs with known hypersensitivity to the manufacturer's importer.
Do not use on dogs with known hypersensitivity to the manufacturer's exporter.
Do not use on dogs with known hypersensitivity to the manufacturer's representative.
Do not use on dogs with known hypersensitivity to the manufacturer's agent.
Do not use on dogs with known hypersensitivity to the manufacturer's distributor.
Do not use on dogs with known hypersensitivity to the manufacturer's importer.
Do not use on dogs with known hypersensitivity to the manufacturer's exporter.



ProMeris[®]
for dogs

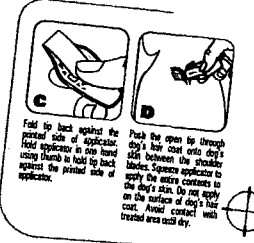
For dogs over 22 pounds
and up to 55 pounds
(> 22-55 lbs)

M

ProMeris[®]
for dogs

For dogs over 22 pounds
and up to 55 pounds
(> 22-55 lbs)

M



M

For dogs over 22 pounds
and up to 55 pounds
(> 22-55 lbs)

Single spot application for control of fleas (and ticks) on dogs 6 weeks of age and older

EA Reg No. 0000-3
EPA Est. No. 61033-1A-001
Net Contents:
6 applicators of 0.1128 oz each

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. See inside pamphlet for label information and directions for use. Read the entire label, directions for use and "How to Apply," instructions before using the product each time. For use on dogs only.

For control of fleas (*Ctenocephalides* sp.) and ticks, apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry. Avoid following the product to come in contact with your skin.

Place empty applicator in trash. Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

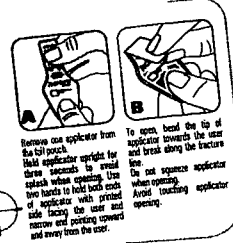
For more information, contact your veterinarian or call the ProMeris[®] for dogs Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

Fort Dodge Animal Health
P.O. Box 25945
Overland Park, KS 66225
MADE IN ITALY

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Fort Dodge intends this product to be sold only by veterinarians and used in established veterinarian/client/patient relationships. Fort Dodge may institute appropriate legal action if this product is sold by persons outside this veterinarian/client/patient relationship.

DO NOT USE ON CATS



ProMeris[®]
for dogs

Calendar Reminder

Date of first treatment	Date of last treatment	Date of first treatment	Date of last treatment	Date of first treatment	Date of last treatment

After the first reminder sticker on your calendar on the first day you treat your dog with ProMeris[®] for dogs immediately apply all the remaining stickers to your calendar to ensure correct intervals for "boost" treatments by marking the dates of each treatment. If the space provided, do not apply more than once a month.

8020013-00
1000007



Lot No.

8 714015 005128

240828

3 pack

PROMERIS
for dogs

Single spot application for control of fleas and ticks on dogs 8 weeks of age and older.

For dogs over 55 pounds and up to 88 pounds (> 55-88 lbs)

CAUTION
KEEP OUT OF REACH OF CHILDREN
Caution: This is a prescription drug. Use only as directed. Do not use if you are pregnant or nursing a child.

INDICATIONS: Fleas and ticks on dogs 8 weeks of age and older.

CONTRAINDICATIONS: Do not use on cats, birds, or other animals.

WARNINGS: Do not use on dogs with known hypersensitivity to any of the ingredients. Do not use on dogs with known hypersensitivity to any of the ingredients.

ADVERSE REACTIONS: None reported.

HOW TO USE: See inside for detailed instructions.

KEEP OUT OF REACH OF CHILDREN. Use only as directed. Do not use if you are pregnant or nursing a child.



PROMERIS
for dogs

For dogs over 55 pounds and up to 88 pounds (> 55-88 lbs)

3 pack

Single spot application for control of fleas and ticks on dogs 8 weeks of age and older.

For dogs over 55 pounds and up to 88 pounds (> 55-88 lbs)

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INDICATIONS: Fleas and ticks on dogs 8 weeks of age and older.

CONTRAINDICATIONS: Do not use on cats, birds, or other animals.

WARNINGS: Do not use on dogs with known hypersensitivity to any of the ingredients. Do not use on dogs with known hypersensitivity to any of the ingredients.

ADVERSE REACTIONS: None reported.

HOW TO USE: See inside for detailed instructions.

KEEP OUT OF REACH OF CHILDREN. Use only as directed. Do not use if you are pregnant or nursing a child.

PROMERIS
for dogs

For dogs over 55 pounds and up to 88 pounds (> 55-88 lbs)

3 pack

Single spot application for control of fleas and ticks on dogs 8 weeks of age and older.

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ADVERSE REACTIONS: None reported.

HOW TO USE: See inside for detailed instructions.

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PROMERIS
for dogs

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ADVERSE REACTIONS: None reported.

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ADVERSE REACTIONS: None reported.

HOW TO USE: See inside for detailed instructions.

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PROMERIS
for dogs

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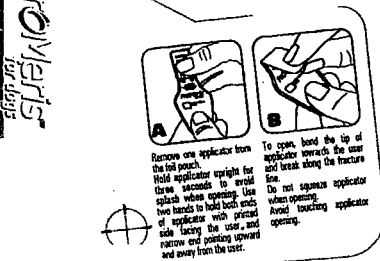
CONTRAINDICATIONS: Do not use on cats, birds, or other animals.

WARNINGS: Do not use on dogs with known hypersensitivity to any of the ingredients. Do not use on dogs with known hypersensitivity to any of the ingredients.

ADVERSE REACTIONS: None reported.

HOW TO USE: See inside for detailed instructions.

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PROMERIS
for dogs

For dogs over 55 pounds and up to 88 pounds (> 55-88 lbs)

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ADVERSE REACTIONS: None reported.

HOW TO USE: See inside for detailed instructions.

KEEP OUT OF REACH OF CHILDREN. Use only as directed. Do not use if you are pregnant or nursing a child.

PROMERIS
for dogs

For dogs over 55 pounds and up to 88 pounds (> 55-88 lbs)

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ADVERSE REACTIONS: None reported.

HOW TO USE: See inside for detailed instructions.

KEEP OUT OF REACH OF CHILDREN. Use only as directed. Do not use if you are pregnant or nursing a child.

PROMERIS
for dogs

For dogs over 55 pounds and up to 88 pounds (> 55-88 lbs)

3 pack

Single spot application for control of fleas and ticks on dogs 8 weeks of age and older.

For dogs over 55 pounds and up to 88 pounds (> 55-88 lbs)

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INDICATIONS: Fleas and ticks on dogs 8 weeks of age and older.

CONTRAINDICATIONS: Do not use on cats, birds, or other animals.

WARNINGS: Do not use on dogs with known hypersensitivity to any of the ingredients. Do not use on dogs with known hypersensitivity to any of the ingredients.

ADVERSE REACTIONS: None reported.

HOW TO USE: See inside for detailed instructions.

KEEP OUT OF REACH OF CHILDREN. Use only as directed. Do not use if you are pregnant or nursing a child.

82J0578

6 pack

ProMeris[™] for dogs

For dogs over 55 pounds and up to 88 pounds (> 55-88 lbs)

CAUTION
KEEP OUT OF REACH OF CHILDREN.
Do not use on cats.

Directions for Use:

- Apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades.
- Do not apply on the surface of dog's hair coat.
- Avoid contact with treated area until dry.
- Avoid allowing the product to come in contact with your skin.
- Place empty applicator in trash.
- Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation.
- Do not apply more than once monthly.

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. See inside pamphlet for label information and directions for use. Read the entire label, directions for use and "How to Apply" instructions before using the product each time. For use on dogs only.

For control of fleas (*Ctenocephalides sp.*) and ticks, apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry. Avoid allowing the product to come in contact with your skin.

Place empty applicator in trash. Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

For more information, contact your veterinarian or call the ProMeris[™] for dogs Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

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P.O. Box 25945
Overland Park, KS 66225
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MADE IN ITALY

DO NOT USE ON CATS

6 pack

For dogs over 55 pounds and up to 88 pounds (> 55-88 lbs)

ProMeris[™] for dogs

Directions for Use:

- Hold applicator upright for three seconds to reveal splash valve opening. Use hand bands to hold both ends of applicator with padded side facing the user and narrow end pointing upward and away from the user.
- To open, bend the tip of applicator towards the user and break along the fracture line. Do not squeeze applicator when opening. Avoid touching applicator opening.

How to Apply:

- Hold applicator in one hand using thumb to hold tip back against the padded side of applicator.
- Push the outer lip through dog's back coat over dog's skin between the shoulder blades. Squeeze applicator to apply the entire contents to the dog's skin. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry.

862003-00
1-00067

8 714015 005067

Lot No.

Calendar Reminder

Date of first treatment	Date of last treatment	Date of last treatment	Date of last treatment	Date of last treatment	Date of last treatment

Apply the first reminder marker to your calendar on the first day you treat your dog with ProMeris for dogs. Immediately apply all the remaining reminder markers to your calendar at 30-day intervals for each treatment by writing the date of each treatment in the spaces provided. Do not apply more than once a month.

26 of 28

3 pack

PROMERIS™
for dogs

CAUTION
KEEP OUT OF REACH OF CHILDREN.
Contains 3 applicators.

ACTIVE INGREDIENTS:
Methoprene (CAS No. 130084-93-0) 1.74%

INERT INGREDIENTS:
2.26%

NET CONTENTS:
3 applicators, 0.225 fl oz each

FOR DOGS OVER 88 POUNDS AND UP TO 110 POUNDS (> 88-110 lbs)



PROMERIS™
for dogs

XL

For dogs over 88 pounds and up to 110 pounds (> 88-110 lbs)

PROMERIS™
for dogs

XL

For dogs over 88 pounds and up to 110 pounds (> 88-110 lbs)

Single spot application for control of fleas and ticks on dogs 6 weeks of age and older

EPA Reg. No. 60490-2
EPA Est. No. 81052-17A-001

Net Contents:
3 applicators of 0.225 fl oz each

DIRECTIONS FOR USE:
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. See inside pamphlet for label information and directions for use. Read the entire label, directions for use and "How to Apply" instructions before using the product each time.

For use on dogs only.

For control of fleas (*Ctenocephalides* sp.) and ticks, apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry. Avoid allowing the product to come in contact with your skin.

Place empty applicator in trash. Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

3 pack

Fort Dodge intends this product to be sold only by veterinarians and used in established veterinarian/client/patient relationships.

Fort Dodge may institute appropriate legal action if this product is sold by persons outside this veterinarian/client/patient relationship.

For more information, contact your veterinarian or call the PROMERIS™ for dogs Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

Fort Dodge Animal Health
P.O. Box 25945
Overland Park, KS 66226

fortdodge

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MADE IN ITALY

DO NOT USE ON CATS

8820021-00
130807



PROMERIS™
for dogs

A

Narrow one applicator from the foil pouch. Hold applicator upright for three seconds to avoid splash when opening. Use two hands to hold both ends of applicator with printed side facing the use and narrow end pointing upward and away from the use.

B

To open, bend the top of applicator between the use and break along the fracture line. Do not squeeze applicator when opening. Avoid touching applicator opening.

C

Fold top back against the printed side of applicator, using thumb to hold top back against the printed side of applicator.

D

Push the open top through dog's hair coat onto dog's skin between the shoulder blades. Squeeze applicator to the dog's skin. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry.

PROMERIS™
for dogs

Calendar Reminder

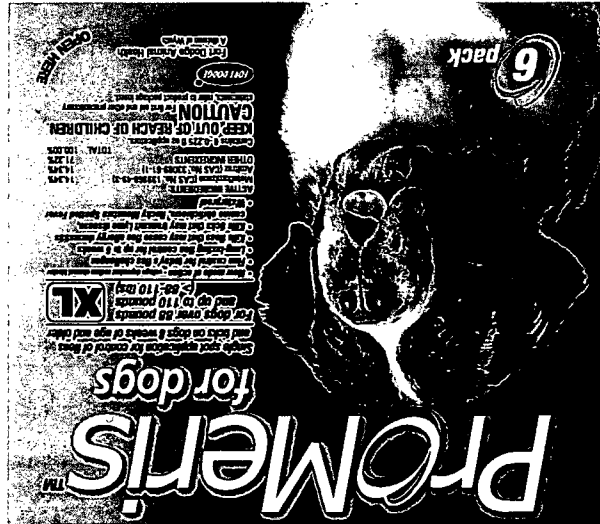
Date of last treatment Date of last treatment Date of last treatment

Apply the first reminder sticker to your calendar on the first day you use your dog with PROMERIS for dogs. Reminders apply only to the calendar stickers on your calendar. Go to www.fortdodge.com for the instructions for the use of each reminder sticker. Do not apply more than once a month.



Lot No.
XXXXXXXXXX

270828



ProMeris[™]
for dogs

For dogs over 88 pounds
and up to 110 pounds
(> 88-110 lbs)

XL

ProMeris[™]
for dogs

For dogs over 88 pounds
and up to 110 pounds
(> 88-110 lbs)

XL

Single spot application for control of fleas and ticks on dogs 8 weeks of age and older.

CPA Reg. No. 00430-2
CPA Est. No. 010537A-001

Net Contents:
6 applicators of 0.225 fl oz each

DIRECTIONS FOR USE:
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. See inside pamphlet for label information and directions for use. Read the entire label, directions for use and "How to Apply" instructions before using the product each time. For use on dogs only.

For control of fleas (*Ctenocephalides* sp.) and ticks, apply the entire contents of the applicator to a single spot on the skin of the dog between the shoulder blades. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry. Avoid allowing the product to come in contact with your hands.

Place empty applicator in trash. Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

For more information, contact your veterinarian or call the **ProMeris[™] for dogs** Consumer Helpline at 1-888-PROMERIS (1-888-776-6374)

Fort Dodge Animal Health
P.O. Box 75945
Overland Park, KS 66225
MADE IN ITALY

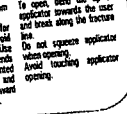
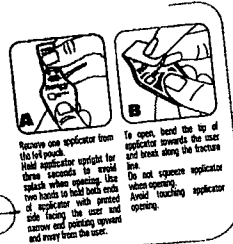
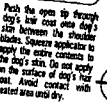
Fort Dodge
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6 pack

Fort Dodge intends this product to be sold only by veterinarians and used in established veterinarian/client/patient relationships.

Fort Dodge may institute appropriate legal action if this product is sold by persons outside this veterinarian/client/patient relationship.

DO NOT USE ON CATS



ProMeris[™]
for dogs

Calendar Reminder

Date of first application	Date of second application	Date of third application	Date of fourth application	Date of fifth application	Date of sixth application

Apply the first monthly tickler to your calendar on the first day you treat your dog with ProMeris[™] for dogs. Immediately apply all the remaining ticklers to your calendar on the same dates. Mark the dates of each treatment in the spaces provided. Do not apply more than once a month.

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Lot No.

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ProMeris™ for dogs



Fort Dodge Animal Health
A division of Wyeth

ProMeris™
for dogs



Fort Dodge Animal Health

Single spot application for control of fleas and ticks on dog and puppies 8 weeks of age and older.

ACTIVE INGREDIENTS:

Metflumizone (CAS No. 139968-49-3)	14.34%
Amitraz (CAS No. 33089-61-1)	14.34%
OTHER INGREDIENTS	71.32%
TOTAL	100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

READ ENTIRE LABEL BEFORE USE

For control of fleas (*Ctenocephalides* sp.) and ticks on dogs and puppies 8 weeks of age and older. ProMeris™ for dogs is a convenient single spot application that provides control of existing flea and tick infestations, and protects against reinfestation. It may also be used to prevent infestation in flea free dogs and puppies 8 weeks of age and older taken into a flea-contaminated environment. Kills fleas that may cause flea allergy dermatitis. Kills and controls the following ticks:

- Black-legged or deer ticks (*Ixodes scapularis*), which can transmit Lyme disease
- Brown dog ticks (*Rhipicephalus sanguineus*), which can transmit *Ehrlichia canis*
- American dog ticks (*Dermacentor variabilis*), which can transmit Rocky Mountain Spotted Fever
- Lone star ticks (*Amblyomma americanum*), which can transmit *Ehrlichia chaffeensis*

A single dose of ProMeris™ for dogs is effective for up to 6 weeks in controlling fleas and up to 4 weeks

for ticks. Apply a single dose prior to exposure. Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly. ProMeris™ for dogs contains two active ingredients – metflumizone and amitraz. Metflumizone provides a high level of control of fleas by blocking gated sodium channels. Amitraz provides control of ticks by affecting octopamine receptors.

Benefits of ProMeris™ for dogs include:

- Stops and controls infestations of fleas and ticks
- Prevents reinfestation of fleas and ticks
- Up to 6 weeks of flea control with a single treatment
- Kills the fleas that may cause flea allergy dermatitis
- Up to 4 weeks of tick control with a single treatment
- Kills ticks that may transmit Lyme disease, canine ehrlichiosis or Rocky Mountain Spotted Fever including brown dog ticks, American dog ticks, lone star ticks, and black-legged or deer ticks
- Convenient and easy to use applicator
- Waterproof
- Effective on indoor or outdoor dogs
- Available only from a licensed veterinary professional
- Pleasant eucalyptus smell

DIRECTIONS FOR USE

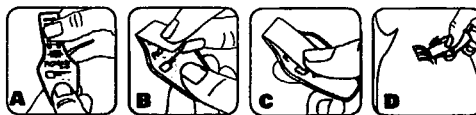
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For external use on dogs and puppies 8 weeks of age and older. DO NOT USE ON ANY ANIMALS OTHER THAN DOGS.

PACKAGING

ProMeris™ for dogs is available in five packaging presentations for different body weights of dogs and puppies 8 weeks of age and older (see table below). Each package contains three or six individual applicator tubes to provide monthly treatments. The dog body weight limits and product volume sizes are specified on individual labels of cartons, foil pouches and applicators.

Package	Dog Size (lbs)	Size (fl) Oz./applicator
XS	Dogs 11 pounds and under (≤ 11)	0.023
S	Dogs over 11 and up to 22 pounds ($> 11-22$)	0.045
M	Dogs over 22 and up to 55 pounds ($> 22-55$)	0.113
L	Dogs over 55 and up to 88 pounds ($> 55-88$)	0.180
XL	Dogs over 88 and up to 110 pounds ($> 88-110$)	0.225

HOW TO APPLY



1. Remove one applicator from the foil pouch.
2. Hold applicator upright for three seconds to avoid splash when opening.
3. Use two hands to hold both ends of applicator with printed side facing the user and narrow end pointing upward and away from the user.
4. To open, bend the tip of applicator towards the user and break along the fracture line.
5. Do not squeeze applicator when opening. Avoid touching applicator opening.
6. Fold tip back against the printed side of applicator. Hold applicator in one hand using thumb to hold tip back against the printed side of applicator.
7. Push the open tip through dog's hair coat onto dog's skin between the shoulder blades. Squeeze applicator to apply the entire contents to the dog's skin. Do not apply on the surface of dog's hair coat. Avoid contact with treated area until dry.
8. Avoid allowing the product to come in contact with your skin.
9. Place empty applicator in trash.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage:

Store in a cool dry place.

Container Disposal:

If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instruction. Never place unused product down any indoor or outdoor drain.

FIRST AID FOR HUMANS

Have the product applicator, carton or this product label with you when contacting a poison control center or medical professional. If swallowed, call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or medical professional. Do not give anything to an unconscious person.

PRECAUTIONARY STATEMENTS

Hazards to Humans

CAUTION

Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Hazards to Domestic Animals

For external use only. For use on dogs only. DO NOT USE ON ANY ANIMALS OTHER THAN DOGS. Do not use on puppies younger than 8 weeks of age. Certain medications can interact with pesticides. Consult a veterinarian before using this product on aged, debilitated, medicated, pregnant or nursing animals. Individual sensitivities, while rare, may occur after the use of any pesticide product. If skin irritation, change in behavior, vomiting or diarrhea is observed and persists after the use of the product, call your veterinarian immediately. For further product information, call 1-888-PROMERIS (1-888-776-6374).

Physical and Chemical Hazards

Combustible. Do not use or store near heat or open flame.

LIMITED WARRANTY AND DISCLAIMER

Directions for use of this product are based upon tests believed to be reliable. The use of this product being beyond control of the seller, no guarantee, express or implied, is made as to the effects of such use or the results to be obtained if not used in accordance with printed directions and established safe practice. To the extent consistent with applicable law, buyer's exclusive remedy and seller's exclusive liability for any and all claims, losses, damages or injuries resulting from the use or handling of this product, whether or not based in contract, negligence, strict liability in tort or otherwise shall be limited, at the seller's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed.

Fort Dodge Animal Health
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MADE IN ITALY

EPA Reg. No. 80490-2
EPA Est. No. 81052-17A-001

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