

80490-2

12/22/2008

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



OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

DEC 22 2008

Bosco Wang
Fort Dodge Animal Health
PO Box 5366
Princeton, NJ 08543-5366

Dear Dr. Wang:

Subject: Amended label to add speed of kill claims for ticks, and instructions for alternate application site at base of skull
ProMeris™ for Dogs
EPA Registration No. 80490-2
Your submission dated September 30, 2008

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A stamped copy is enclosed for your records. Submit two copies of your final printed labeling before you release the product for shipment. If you have any questions, please contact Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Regards,

A handwritten signature in black ink, appearing to read "John Hebert".

John Hebert
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA Reg. No: 80490-2

ProMeris®

for dogs



Fort Dodge Animal Health
A division of Wyeth

ProMeris®
for dogs



Single spot application for control of fleas, ticks, chewing lice and Demodectic mange mites on dogs and puppies 8 weeks of age and older.

ACTIVE INGREDIENTS:

Metafumizone (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* spp.), ticks, chewing lice and Demodectic mange mites 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, tick, chewing lice and Demodectic mange mite infestations, and protects against reinfestation of fleas, ticks and chewing lice. 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, lice and mange mites:

- 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*
- Chewing lice (*Trichodectes canis*)
- Demodex mites (*Demodex* spp.), which can cause Demodectic mange

Start killing ticks within 4 hours. Rapidly kills most tick species within 24 hours.

ProMeris® for dogs can be used in breeding males, as well as breeding and pregnant bitches. Do not use on lactating/nursing bitches until at least 5 days after delivery.

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, ticks, chewing lice and Demodectic mange mites and to prevent reinfestation of fleas, ticks and chewing lice. Do not apply more than once monthly. ProMeris® for dogs contains two active ingredients – metafumizone and amitraz. Metafumizone provides a high level of control of fleas and chewing lice by blocking gated sodium channels. Amitraz provides control of ticks and Demodectic mange mites by affecting octopamine receptors.

Benefits of ProMeris® for dogs include:

- Stops and controls infestations of fleas, ticks, chewing lice and Demodectic mange mites
- Prevents reinfestation of fleas, ticks and chewing lice
- Up to 6 weeks of flea control with a single treatment
- Kills 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
- Starts killing ticks within 4 hours
- Rapidly kills most tick species within 24 hours
- Kills chewing lice
- Kills mites that may cause Demodectic mange
- 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

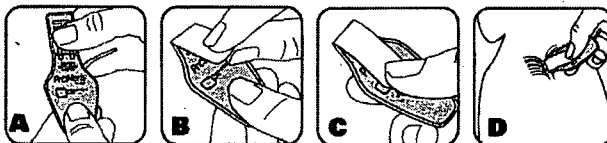
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For external use on dogs and puppies 8 weeks of age and older. DO NOT USE ON ANY ANIMALS OTHER THAN DOGS.

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)	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 at the base of the skull or 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 in 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 or medicated 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

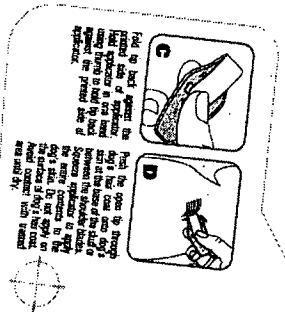
Directions for use of this product are based upon tests believed to be reliable. The use of this product being beyond control of the seller, no guarantee, express or implied, is made as to the effects of such use or the results to be obtained if not used in accordance with printed directions and established 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
P.O. Box 25945
Overland Park, KS 66225

MADE IN ITALY

EPA Reg. No. 80490-2
EPA Est. No. 81052-ITA-001

Handwritten initials: NS



Promeris[®] for dogs

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



Fort Dodge Inteva this product is sold only by veterinarians, veterinary clinics, and pet stores. For more information, contact your veterinarian or call the Promeris[®] for dogs Consumer Helpline at 1-888-PROMERIS (1-888-798-6374).

DO NOT USE ON CATS

Promeris[®] for dogs

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

Promeris[®] for dogs



KEEP OUT OF REACH OF CHILDREN. CAUTION: For use only on dogs. Do not use on cats. For more information, contact your veterinarian or call the Promeris[®] for dogs Consumer Helpline at 1-888-PROMERIS (1-888-798-6374).

DIRECTIONS FOR USE: This is a violation of Federal law to use this product in a manner inconsistent with its labeling. See inside packaging for detailed 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 felis), ticks (Ixodes ricinus and Dermacentor variabilis), apply the entire contents of the applicator to a single spot on the skin of the dog at the base of the skull or 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.

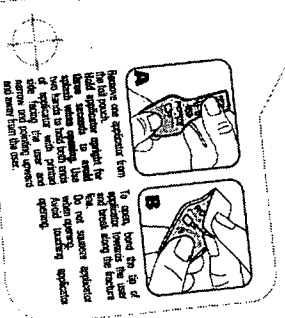
Please apply applicator in treat. Monthly application is recommended for effective control of fleas, ticks, chewing lice and Demodexic mange mites and to prevent reinfestation of fleas, ticks and chewing lice. Do not apply more than once monthly.

For more information, contact your veterinarian or call the Promeris[®] for dogs Consumer Helpline at 1-888-PROMERIS (1-888-798-6374).

For Dogs: Fort Dodge Animal Health, P.O. Box 2046, Overland Park, KS 66223, Kansas 66174, USA. © 2005 Fort Dodge Animal Health, a division of Wyeth. All rights reserved.



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Promeris[®] for dogs

Calendar Reminder

Date of last treatment: _____

Date of next treatment: _____

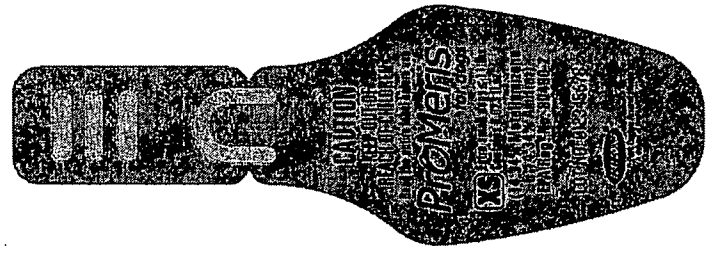
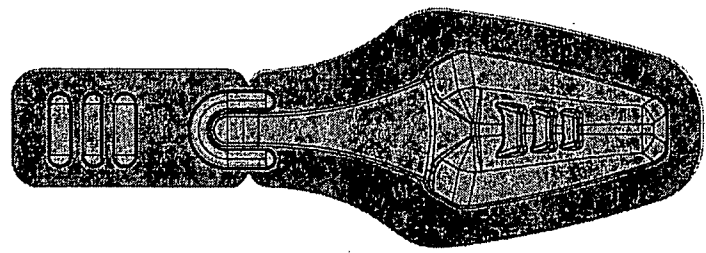
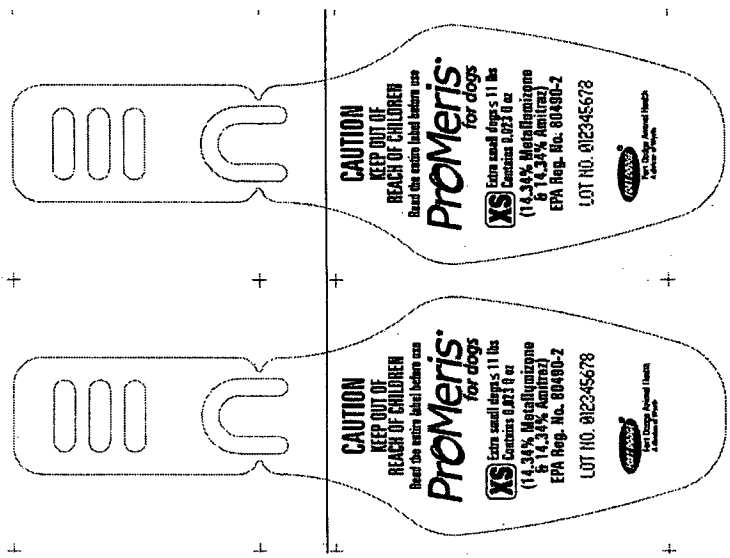
Apply the first treatment according to your calendar and the label. Then, you must repeat this treatment for dogs, cats, and puppies every 30 days. Do not use on cats. Do not use on puppies less than 6 weeks of age. Do not use on puppies less than 2 weeks of age. Do not use on puppies less than 2 weeks of age.



8 4 2 0 0 7 6

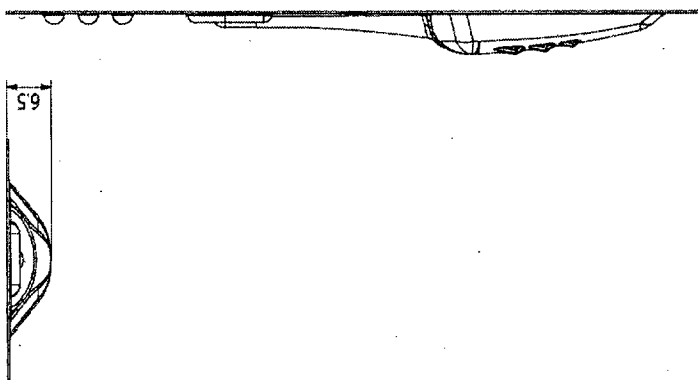
Lot No. XXXXXXXXXX

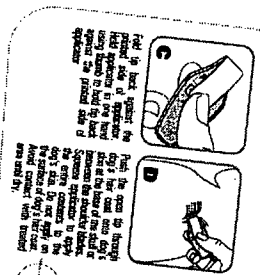




65

77





Promeris[®] for dogs
 For dogs over 11 pounds and up to 22 pounds (5-11-22 lbs)

6 pack

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

Port Dodge Animal Health, P.O. Box 2696, Channahon, IL 61615, USA
 MADE IN ITALY



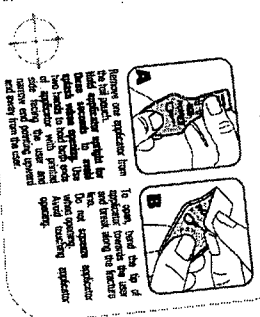
Promeris[®] for dogs

For dogs over 11 pounds and up to 22 pounds (5-11-22 lbs)

6 pack

KEEP OUT OF REACH OF CHILDREN. CAUTION

Port Dodge Animal Health, P.O. Box 2696, Channahon, IL 61615, USA
 MADE IN ITALY



Promeris[®] for dogs
 For dogs over 11 pounds and up to 22 pounds (5-11-22 lbs)

Promeris[®] for dogs

Calendar Reminder

Apply the product to your dog's back, neck, and chest every month. Do not apply the product to your dog's face, eyes, or ears.

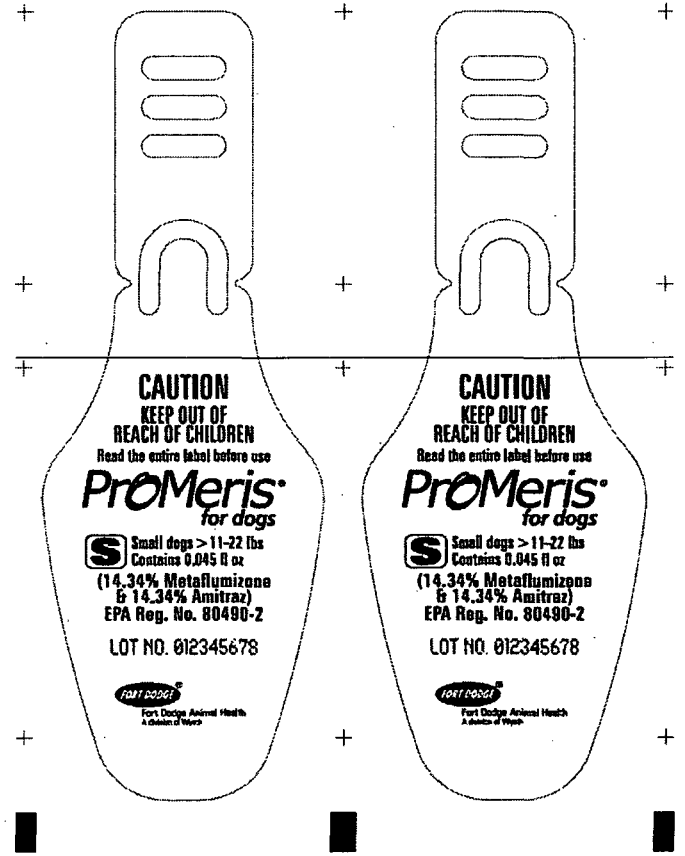
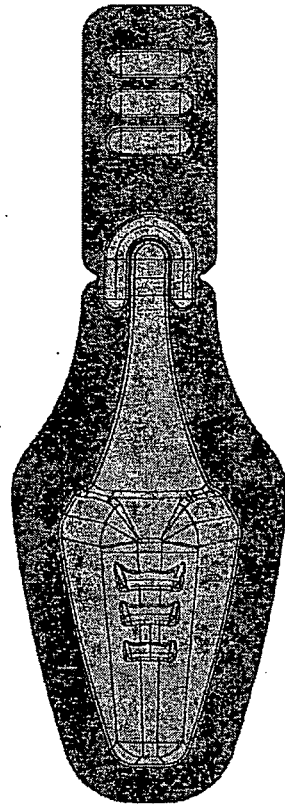
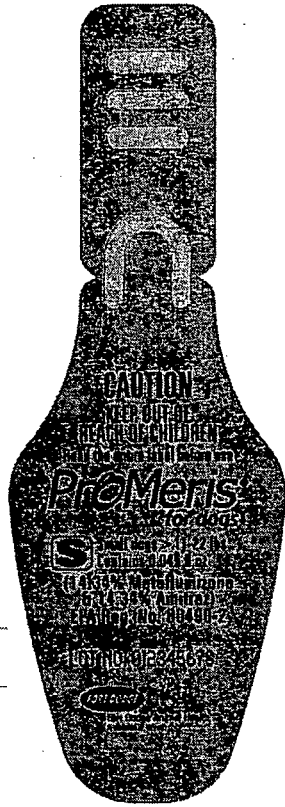
Month	Day	Time	Time	Time	Time	Time
Jan	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
Feb	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
Mar	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
Apr	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
May	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
Jun	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
Jul	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
Aug	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
Sep	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
Oct	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
Nov	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM
Dec	1	10:00 AM	10:00 AM	10:00 AM	10:00 AM	10:00 AM

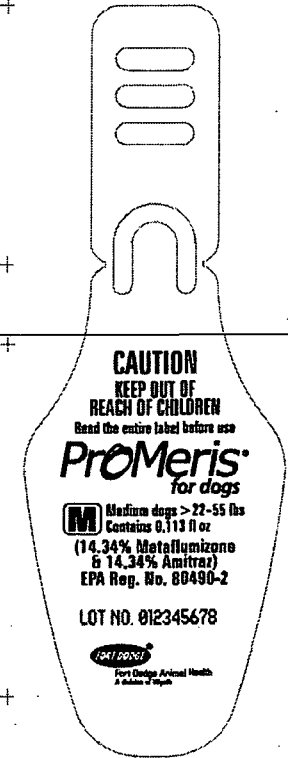
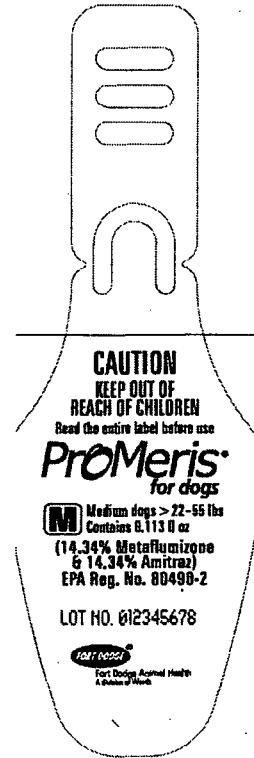
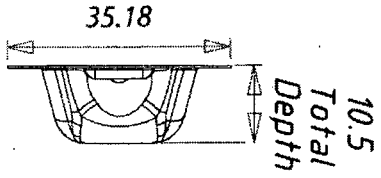
Port Dodge Animal Health, P.O. Box 2696, Channahon, IL 61615, USA
 MADE IN ITALY





7.4





17/25

16/25

6 pack

PROMERIS[®] for dogs

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

1

PROMERIS[®] for dogs

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

1

PROMERIS[®] for dogs

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

FOR MORE INFORMATION, CONTACT YOUR VETERINARIAN OR CALL THE PROMERIS[®] FOR DOGS CONSUMER HELPLINE AT 1-888-PROMERIS (1-888-776-6374)

FOR DODGE ANIMAL HEALTH
P.O. Box 25945
Overland Park, KS 66226
MADE IN ITALY

8820054-04
230808

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PROMERIS[®] for dogs

FOR DODGE ANIMAL HEALTH

1

PROMERIS[®] for dogs

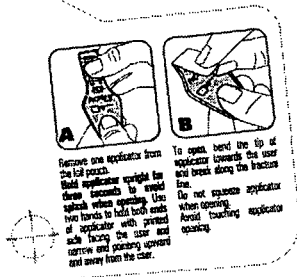
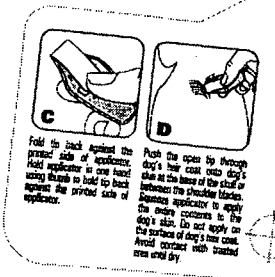
Calendar Reminder

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

Apply the last reminder sticker to your calendar on the last day you treat your dog with Promeris[®] for dogs. Immediately notify us if the reminder sticker is your calendar at convenient intervals for each treatment on the date of each treatment in the spaces provided. Do not apply more than one sticker.

8 714015 005067

Lot No.
XXXXXXXXXXXX



Single spot application for control of fleas, ticks, chewing lice and Demodex mange mites on dogs and puppies 8 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* spp.), ticks, chewing lice and Demodex mites, apply the entire contents of the applicator to a single spot on the skin of the dog at the base of the skull or 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, ticks, chewing lice and Demodex mange mites and to prevent reinestation of fleas, ticks and chewing lice. 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)

FOR DODGE ANIMAL HEALTH
P.O. Box 25945
Overland Park, KS 66226
MADE IN ITALY

8820054-04
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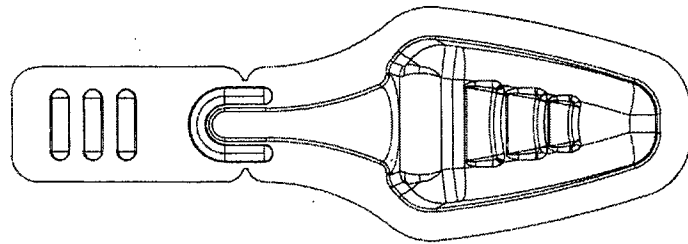
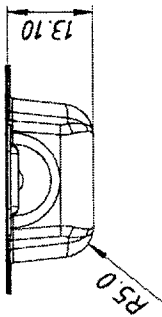
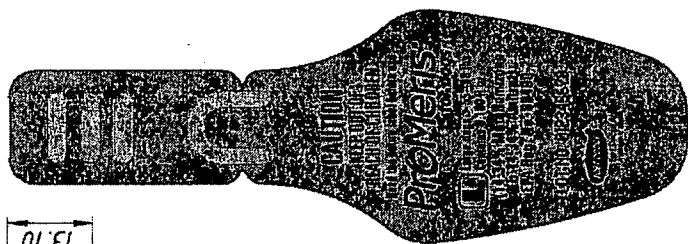
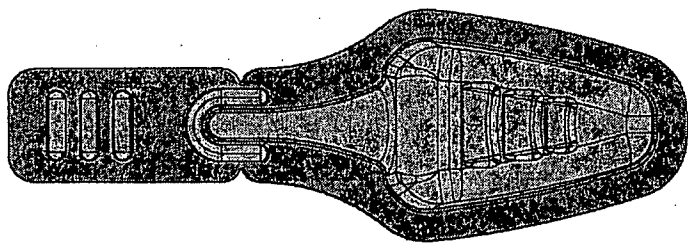
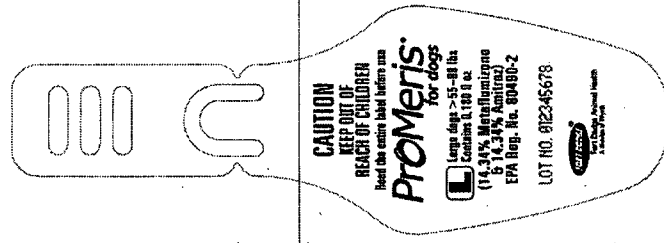
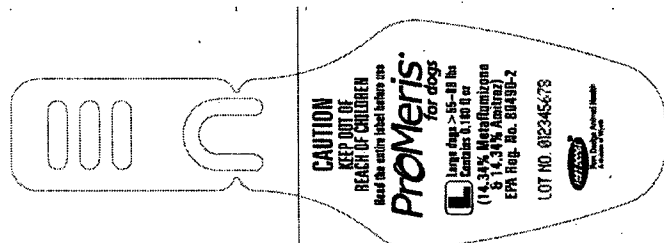
PROMERIS[®] for dogs

Calendar Reminder

Apply the last reminder sticker to your calendar on the last day you treat your dog with Promeris[®] for dogs. Immediately notify us if the reminder sticker is your calendar at convenient intervals for each treatment on the date of each treatment in the spaces provided. Do not apply more than one sticker.

8 714015 005067

Lot No.
XXXXXXXXXXXX



20/25

PROMERIS[®] for dogs

pack

TX

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

CAUTION KEEP OUT OF REACH OF CHILDREN

For Dogs Over 88 Pounds and up to 110 Pounds (> 88-110 lbs)

Single spot application for control of fleas, ticks, chewing lice and Demodex mites on dogs and puppies 8 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* spp.), ticks, chewing lice and Demodex mites, apply the entire contents of the applicator to a single spot on the skin of the dog at the base of the skull or 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, ticks, chewing lice and Demodex mites and to prevent reinfestation of fleas, ticks and chewing lice. 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
Overland Park, KS 66226
MADE IN ITALY

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PROMERIS[®] for dogs

XL

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

pack

TX

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

Single spot application for control of fleas, ticks, chewing lice and Demodex mites on dogs and puppies 8 weeks of age and older.

EPA Reg. No. 80494-2
EPA Est. No. 81052-ATA-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* spp.), ticks, chewing lice and Demodex mites, apply the entire contents of the applicator to a single spot on the skin of the dog at the base of the skull or 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, ticks, chewing lice and Demodex mites and to prevent reinfestation of fleas, ticks and chewing lice. 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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Overland Park, KS 66226
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a division of Wyeth. All rights reserved.

PROMERIS[®] for dogs

XL

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

Calendar Reminder

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

Date of first treatment	Date of next treatment	Date of next treatment	Date of next treatment	Date of next treatment	Date of next treatment

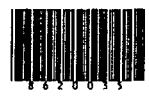
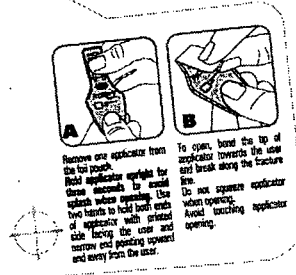
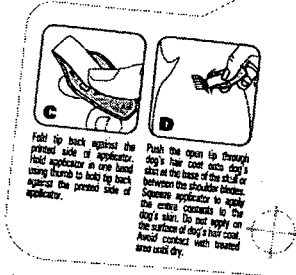
How to Apply:
A: Remove one applicator from the foil pack. Hold applicator upright for three seconds to seal. Do not splash when opening. Use two hands to hold both ends of applicator with greatest side facing the user and narrow end pointing upward and away from the user.
B: To open, bend the tip of applicator towards the user and break along the fracture line. Do not separate applicator when opening. Avoid touching applicator opening.

How to Apply:
C: Fold lip back against the printed side of applicator. Hold applicator in one hand using thumb to hold lip back against the printed side of applicator.
D: Push the open lip through dog's hair coat onto dog's skin at the base of the skull or 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.

DO NOT USE ON CATS

8 714015 005241

Lot No. XXXXXXXXXX



B0063-01 DOG XL USA

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

Promeris[®]
 for dogs



Extra large dogs > 88-110 lbs
 Contains 0.225 fl oz (14.34% Meprobamate, 614.34% Amitriptyline)
 EPA Reg. No. 80490-2

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



sq 0.11-88 < stop along extra
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Extra large dogs > 88-110 lbs
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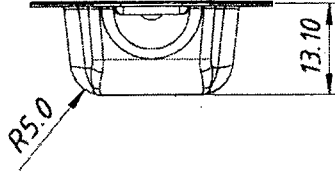
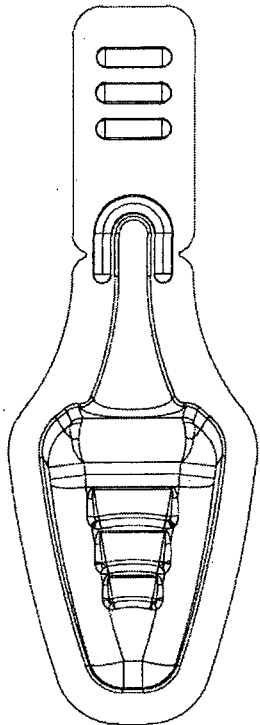
Promeris[®]
 for dogs



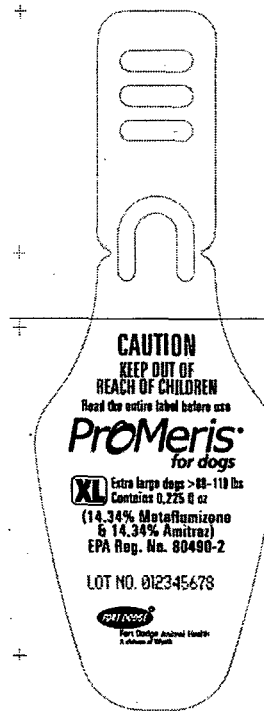
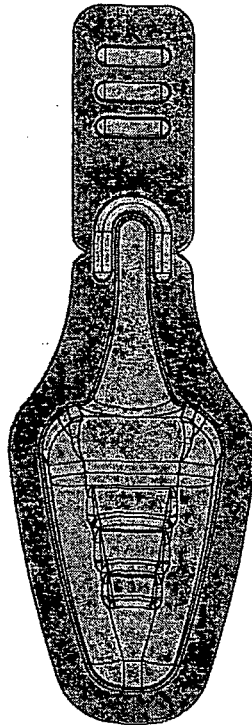
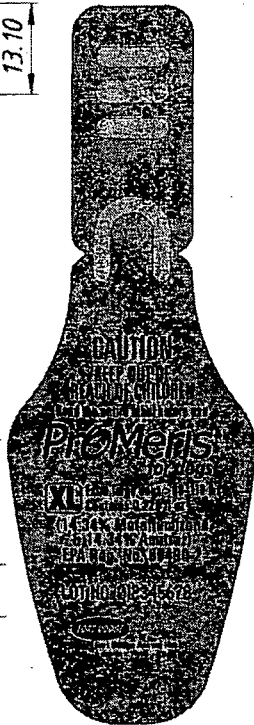
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Fort Dodge Animal Health
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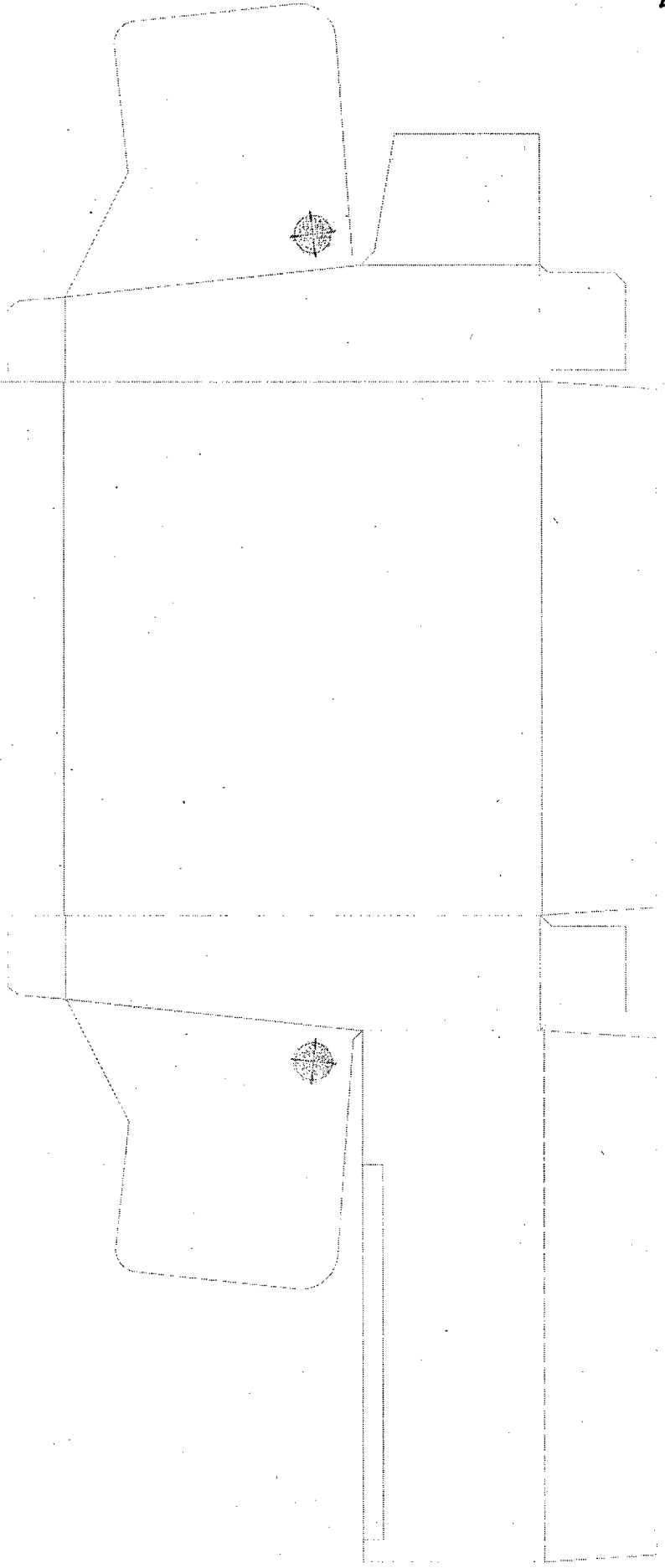
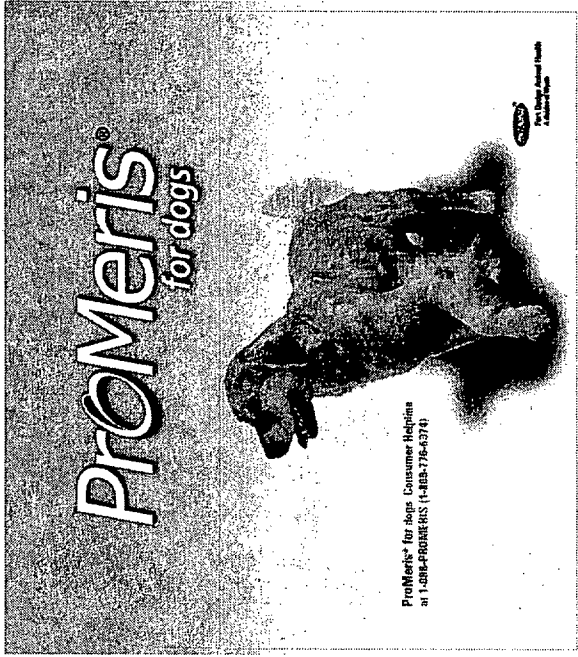
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XL Extra large dogs > 89-119 lbs
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(14.34% Metflumizone
& 14.34% Amitraz)
EPA Reg. No. 80490-2
LOT NO. 012345678
ENTROSOFT
Fort Dodge Animal Health
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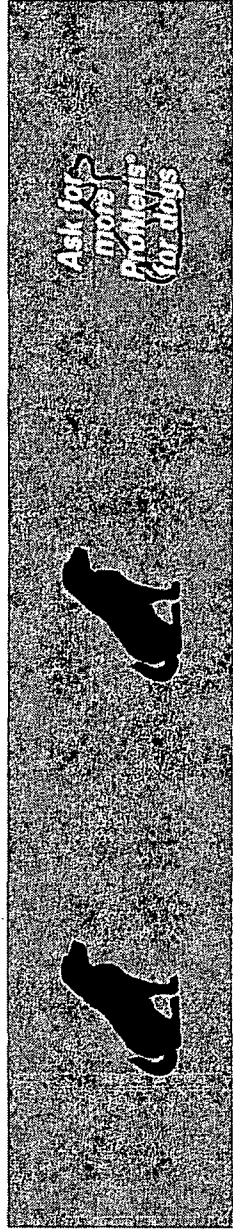
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ProMeris for dogs



ProMeris for dogs

