

January 25, 2012

IMPORTANT PRODUCT INFORMATION

Dear Doctor:

Novartis Animal Health US, Inc. is committed to delivering safe and efficacious veterinary products, and would like to inform you about a recent development involving CLOMICALM® (clomipramine hydrochloride) tablets.

Due to potential packaging issues at our manufacturing facility, there is a rare possibility that a wrong tablet may be found in bottles of CLOMICALM with the enclosed lot numbers. Novartis has not received any reports where a patient experienced a product mix-up, nor has Novartis received any adverse events attributable to a product mix-up. However, as a precautionary measure, we would like to extend the following recommendations.

- 1) Before dispensing CLOMICALM, open each bottle and examine the contents for tablets that are broken or incorrect in color, shape or size (visual guide included).
- 2) Post a copy of the Dear Valued Customer letter issued by Novartis Animal Health in your clinic (copy included).
- 3) Distribute copies of the Dear Valued Customer letter to affected pet owners. Novartis Animal Health will send your clinic extra copies upon request. If you publish a clinic newsletter, please consider using the provided notice.
- 4) Report any abnormal findings to Novartis Animal Health at 800-637-0281.
- 5) Return affected product to Novartis Animal Health; call the aforementioned number for full details.
- 6) Inform your clients who have already received CLOMICALM to examine tablets and refrain from administering any that are questionable in color, shape or size; and to contact Novartis Animal Health to discuss product return of affected bottles.
- 7) Keep records of communication with pet owners in patient files.
- 8) Ensure that any re-packaged tablet bottles are labeled with the product lot number.

Novartis Animal Health requests that you complete and return the enclosed Response Card reflecting that you have read and understand these points, and have discussed them with your clients.

Canine separation anxiety is a complex disorder that has great bearing on patient quality of life and the human-companion animal bond. Uninterrupted treatment is essential for successful management of this condition. Our veterinarians are prepared to discuss best practices with you in the event patients require alternative therapies, in order to minimize the risk of adverse events and potential relapse of signs.

We thank you for your attention and cooperation regarding this important issue. If you have any further questions, please contact Technical Product Services and Pharmacovigilance at 1-800-637-0281.

Sincerely,



Doug Reece, DVM
Medical Director
NAHUS, Inc.



Cynthia McCants
Head of Quality Operations
NAHUS, Inc.

Enclosures:

Dear Valued Customer Letter
Clomicalm Lots
Clomicalm Tablets Size
NAH Response Card
Notice for Clinic Newsletter

CLOMICALM LOTS

January 25, 2012

Clomicalm® (clomipramine hydrochloride) 5mg
(NDC number: 058198-4030-2)

NAH Lot #	Expiration Date	Bottle Size
10098776	September 2013	30 Count

Clomicalm® (clomipramine hydrochloride) 20 mg
(NDC number: 058198-4031-2)

NAH Lot #	Expiration Date	Bottle Size
10122354	August 2014	30 Count
10098779	October 2013	30 Count
10085841	June 2013	30 Count
10079205	October 2012	30 Count
10072783	July 2012	30 Count
10063973	February 2012	30 Count

Clomicalm® (clomipramine hydrochloride) 40 mg
(NDC number: 058198-4032-2)

NAH Lot #	Expiration Date	Bottle Size
10120764	August 2014	30 Count
10098775	October 2013	30 Count
10092743	August 2013	30 Count
10082033	January 2013	30 Count
10072784	July 2012	30 Count
10061894	February 2012	30 Count

Clomicalm® (clomipramine hydrochloride) 80 mg
(NDC number: 058198-4033-2)

NAH Lot #	Expiration Date	Bottle Size
10125584	October 2014	30 Count
10115214	June 2014	30 Count
10098781	October 2013	30 Count
10092746	July 2013	30 Count
10082034	January 2013	30 Count
10072785	September 2012	30 Count
10065183	February 2012	30 Count