Boehringer Ingelheim

September 17, 2010

Dear Doctor:

At Boehringer Ingelheim Vetmedica, Inc. (BIVI), we are committed to providing you with the knowledge you need to prescribe our products with confidence. We are sending this letter to share new information about the use of Metacam® (meloxicam) in cats.

Since its introduction in the U.S. in 2003, METACAM has been used safely and effectively in hundreds of thousands of dogs and cats.

METACAM Oral Suspension is not licensed in the U.S. for use in cats. Unfortunately adverse events in cats do occur. These have been reported at a consistent level over the past 5 years and the majority following the inappropriate off-label administration of the more concentrated 1.5 mg/mL formulation in cats.

BIVI and FDA-CVM have agreed to provide important new feline safety information to the product label. The product inserts for METACAM Solution for Injection and METACAM Oral Suspension will carry the following statement:

Warning: Repeated use of meloxicam in cats has been associated with acute renal failure and death. Do not administer additional doses of injectable or oral meloxicam to cats. See Contraindications, Warnings and Precautions for detailed information.

The warning does not affect the approved indications for single use of METACAM Solution for injection in cats for the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration when administered prior to surgery. Indications for acute and chronic use in dogs remain unchanged. Included are copies of the full updated product and client information sheets (see reverse side for complete list of changes).

For a current expert consensus regarding analgesia in cats, including the use of NSAIDs, please refer to the guidelines of the American Association of Feline Practitioners (www.aafponline.org).

BIVI remains committed to providing the highest quality products to assist practicing veterinarians in promoting and preserving the human animal bond. We will continue to keep you updated on all of our products. If you have any questions, please call our Veterinary Technical Services team at 1-866-638-2226.

Thank you for your continued support.

Sincerely,

James B. Hall, D.V.M.

Dr. James Hall
Sr. Associate Director Veterinary Technical Services

Sincerely,

Kurt D. Peterson DVM

Dr. Kurt Peterson
Technical Marketing Manager – Pet

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Summary of changes to Metacam Insert Labels and Client Information Sheet

Metacam® (meloxicam) Oral Suspension, 0.5 & 1.5 mg/ml, NADA 141-213

Although this product is not labeled for use in cats, we are strengthening the information given on the package insert and the client information sheet regarding the fact that Metacam® (meloxicam) Oral Suspension should not be used in cats, as follows (See attached Package Insert and Client Information Sheet):

On the Package Insert:

1) Updated the Contraindications section
2) Added a Boxed Warning
3) Updated the Post-Approval Experience section
4) Updated the Information for Dog Owners section

On the Client Information Sheet:

1) Updated the answer to the section: "What is Metacam?"
2) Updated the answer to the section: "What Else Should I Know About Metacam?",

Metacam® (meloxicam) 5mg/ml Solution for Injection, NADA 141-219

Metacam® (meloxicam) 5mg/ml Solution for Injection is labeled for the use in dogs as a one-time injection that can be followed, after 24 hours, by daily administration of Metacam® Oral Solution. Metacam® (meloxicam) 5mg/ml Solution for Injection is labeled for the use in cats as a **single one-time administration subcutaneous dose** that should **not** be followed by additional doses of meloxicam or other NSAIDs. The Package Insert has been updated as follows (See attached Package Insert for Dogs and for Cats):

Package Insert for Cats:

1) Updated the Contraindications section
2) Added a Boxed Warning
3) Updated the warnings section
4) Updated and divided the Precautions section into more legible paragraphs
5) Added a Post-Approval Experience section

Package Insert for Dogs:

1) Added a Boxed Warning,
2) Updated the Post-Approval Experience Section