

Date of Approval: April 5, 2023

**FREEDOM OF INFORMATION SUMMARY**  
**ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION**

ANADA 200-612

Bimasone™

(flumethasone)

Injectable solution

Horses, Dogs and Cats

Bimasone™ is recommended for the various rheumatic, allergic, dermatologic and other disease states which are known to be responsive to the anti-inflammatory corticoids.

Sponsored by:

Bimeda Animal Health Ltd.

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**I. GENERAL INFORMATION**

**A. File Number**

ANADA 200-612

**B. Sponsor**

Bimeda Animal Health Ltd.  
1 B The Herbert Building  
The Park, Carrickmines,  
Dublin, 18 Ireland

Drug Labeler Code: 061133

U.S Agent Name and Address:

Ms. Deb Ann Voss  
Bimeda Inc.  
291 Forest Prairie Road  
Le Sueur, MN 56058

**C. Proprietary Name**

Bimasone™

**D. Drug Product Established Name**

flumethasone

**E. Pharmacological Category**

Anti-inflammatory

**F. Dosage Form**

Injectable solution

**G. Amount of Active Ingredient**

0.5 mg/mL

**H. How Supplied**

100 mL multi-dose vials

**I. Dispensing Status**

Prescription (Rx)

**J. Dosage Regimen**

*Equine:* 1.25 to 2.5 mg daily by intravenous, intramuscular or intra-articular injection. If necessary, the dose may be repeated.

*Canine:* 0.0625 to 0.25 mg daily by intravenous, intramuscular or subcutaneous injection. If necessary, the dose may be repeated. With chronic conditions, the preceding doses may be used and oral maintenance therapy with flumethasone tablets instituted at a daily dose of 0.0625 to 0.25 mg. Intra-lesional dosages in the dog have ranged from 0.125 to 1 mg depending on the size and location of the lesion under treatment. Intra-articular dosages in the dog have ranged from 0.166 to 1 mg depending on the severity of the condition under treatment and the size of the involved joint.

*Feline:* 0.03125 to 0.125 mg by intravenous intramuscular or subcutaneous injection. If necessary, the dose may be repeated. With chronic conditions, the preceding injectable doses may be used and oral maintenance therapy with flumethasone tablets instituted at a daily dosage of 0.03125 to 0.125 mg.

#### **K. Route of Administration**

Horses: Intravenous, intramuscular, or intra-articular injection

Dogs: Intravenous, intramuscular, intra-lesional, or subcutaneous injection

Cats: Intravenous, intramuscular, or subcutaneous injection

#### **L. Species/Class**

Horses, dogs and cats

#### **M. Indications**

Bimasone™ is recommended for the various rheumatic, allergic, dermatologic and other disease states which are known to be responsive to the anti-inflammatory corticoids:

##### *Equine Indications :*

1. Musculoskeletal conditions due to inflammation, where permanent structural changes do not exist, such as bursitis, carpalitis, osselets and myositis. Following therapy an appropriate period of rest should be instituted to allow a more normal return to function of the affected part.
2. In allergic states such as hives, urticaria and insect bites.

##### *Canine Indications:*

1. Musculoskeletal conditions due to inflammation of muscles or joints and accessory structures, where permanent structural changes do not exist, such as arthritis, osteoarthritis, the disc syndrome and myositis. In septic arthritis appropriate antibacterial therapy should be concurrently administered.
2. In certain acute and chronic dermatoses of varying etiology to help control the pruritus, irritation and inflammation associated with these conditions. The drug has proven useful in otitis externa in conjunction with topical medication for similar reasons.
3. In allergic states such as hives, urticaria and insect bites.
4. Shock and shock-like states, by intravenous administration.

*Feline Indications:*

1. In certain acute and chronic dermatoses of varying etiology to help control the pruritus, irritation and inflammation associated with these conditions.

**N. Reference Listed New Animal Drug (RLNAD)**

Flucort®; flumethasone; NADA 030-414; Zoetis Inc.

**II. BIOEQUIVALENCE**

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Bimeda Animal Health Ltd., was granted a biowaiver for the generic product Bimasone™ (flumethasone) sterile injection. The generic drug product is an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is Flucort® (flumethasone) solution, sponsored by Zoetis Inc., under NADA 030-414, and was approved for use in horses, dogs and cats on October 21, 1965.

**III. HUMAN FOOD SAFETY**

This drug is intended for use in horses, dogs and cats. Because this new animal drug is not intended for use in food-producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this ANADA.

The product labeling contains the following Warning statement: Not for use in horses intended for human consumption.

**IV. USER SAFETY**

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Bimasone™:

**NOT FOR USE IN HUMANS. KEEP OUT OF REACH OF CHILDREN.**

**V. AGENCY CONCLUSIONS**

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Bimasone™, when used according to the label, is safe and effective for the indications listed in Section I.M. above.