

**FEDERAL DRUG ADMINISTRATION**

**DETERMINATION OF ELIGIBILITY FOR INDEXING OF LEGALLY MARKETED  
UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES**

**F10 GERMICIDAL BARRIER OINTMENT**

**Modification to previous submission Ref Z-900009**

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### 1. Identification of minor species groups

Regarding Bumble foot in pet birds and raptors species that are kept in cages and aviaries and as a topical antiseptic in multiple non-food-producing minor species including Felidae, excluding the domestic cat; captive non-food-producing minor species hoof stock; non-human primates; captive Ursidae; elephants; hippopotamuses; hyenas; and captive tortoises.

### 2. Composition and dosage form

#### 2.1 Pharmaceutical category

Antiseptic ointment

#### 2.2 Dosage form

Ointment

#### 2.3 Composition

##### Actives

Alkyl Dimethyl Benzyl Ammonium Chloride	0.405g/100g
Poly (Hexamethylene Biguanide) Hydrochloride	0.03g/100g

##### Excipients

C10 alcohol Ethoxylate	0.19g/100g
Tetrasodium ethylene diamine tetra acetic acid	0.09g/100g
Glycol	88.50g/100g
Lanolin	4.00g/100g
Water	to balance

### 3. Intended uses

3.1 For the prevention of Bumble foot (Pododermatitis) by controlling pathogens on birds feet which cause disease and are not normal commensals e.g. *S aureus* in those species that are particularly prone to this disease such obese and inactive cage birds and captive birds of prey, and

3.2 For the treatment of Stage 1 Bumble foot, i.e. lesion or inflammation due to pressure sores affecting the ball of the foot or one or more toes with concurrent secondary bacterial infections: *Staphylococcus aureus*, *E.coli*, *Pseudomonas* spp, and

3.3 For use as a topical antiseptic of wounds in multiple non-food-producing minor species including Felidae, excluding the domestic cat; captive non-food-producing minor species hoof stock; non-human primates; captive Ursidae; raptors; elephants; hippopotamuses; hyenas; and captive tortoises.

## **4. Conditions of use**

### **4.1 Dosage**

4.1.1 As a preventative it is advised to apply a layer of ointment to the plantar foot and digits of the feet twice a week.

4.1.2 For the treatment of stage 1 Bumble foot, after prior skin cleansing with an antiseptic solution, the application of a layer of ointment daily to the whole of the feet to stimulate healing and control pathogens.

4.1.3 In the advanced bumblefoot (stages 3 to 5) to apply the ointment at each change of the wound dressing after first irrigating the site with the antiseptic solution. Where 'corn plaster style' padded dressings are applied to the feet, ointment can be applied to the exposed skin in the centre of the dressing on a daily basis.

4.1.4 As a topical antiseptic apply the ointment to a dressing or directly to the surface of the wound whichever is most appropriate after first irrigating the site with the antiseptic solution and repeat daily.

### **4.2 Route of administration**

4.2.1 Topical application

### **4.3 Contra Indications**

None

### **4.4 Warnings**

None required

### **4.5 Presentation**

25g tubes and 100g pots in HDPE

### **4.6 How dispensed**

Over the counter (OTC)

## **5. Needs and benefits**

Bumble foot, ('Pododermatitis') is a very common disease that can affect all captive birds which are obese or inactive for long periods. It is commonest in falcons, occasional in eagles and owls and rare in hawks and others. The condition may rarely arise secondary to a penetration or abrasion, but is very commonly linked to a pressure necrosis effecting the plantar aspect of the foot. The pressure necrosis results in a breach of the dermal defence mechanism, such that pathogens on the skin, can traverse the barrier and set up localised or generalised cellulitis in the foot.

Regular applications of the broad spectrum, long acting, F10 Germicidal Barrier Ointment as part of good husbandry can prevent its occurrence and it is often adequate to prevent progression and allow resolution when used in Stage I.

In the post-surgical stages of Bumble foot, Stages II to V, and as a topical antiseptic treatment in other minor species, as an adjunct to promote healing and prevent infection.

## **6. Estimated annual distribution of active ingredients**

AVMA statistics for 2007 gave the total number of pet birds in the USA as 11,199,000.

For the purpose of this estimate an average infection rate of 0.25% is assumed, i.e. 27,995 birds, a 2/3 week course of treatment, with a daily application resulting in the administration of 20g of the ointment per bird thus giving a national consumption of 560kg, which equates to 2.25 kg of Alkyl Dimethyl Benzyl Ammonium Chloride and 0.15kg of Poly (Hexamethylene Biguanide) Hydrochloride.

Allowing for preventative applications at a rate of 0.5% for 12 months per annum, applied at a rate of 240g/bird of ointment over the period would increase total usage to 14,000 kg of ointment which equates to 56 kg of Alkyl Dimethyl Benzyl Ammonium Chloride, and 4 kg of Poly (Hexamethylene Biguanide) Hydrochloride.

The usage as a topical antiseptic in the minor species nominated would increase estimated potential usage by 50%.

## **7. Exclusion of species used for human consumption**

Re Bumble foot, the species groups nominated are pet cage birds and in the larger pet species those kept in aviaries. For this purpose raptors are also included.

Re the expansion of the label to include more minor species animals these application should be restricted to exclude all species used for human consumption.

## **8. Manufacturing facility**

Manufacture is carried out in a GMP facility licensed to manufacture non-sterile veterinary medicines. For full details refer to Appendix A included in submission Z-900009.

## **9. User safety**

Product specific animal studies to establish toxicity in the actives concentrate solution showed toxicity levels to be low.

Tests carried out to EPA toxicity protocols showed the following:

- Acute oral toxicity (rats) - >5000mg/kg
- Acute dermal toxicity (rats) - >5000mg/kg
- Acute dermal irritation (guinea pigs) - none
- Acute eye irritation (rabbits) - moderate
- Acute sensitization (guinea pigs) – none
- Acute inhalation toxicity (rats) – n/a

## **10. US Agent**

For the purposes of this eligibility application the US Agent of Health and Hygiene (Pty)

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