

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Carton)**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Stomorgyl 10 Film-coated tablets

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains 234.4 mg spiramycin of standard potency (3,200 IU/mg), and 125 mg metronidazole in an inert carrier.

Colorants: Ponceau 4R, 0.06 mg; Titanium dioxide E171, 0.20 mg.

### **3. PHARMACEUTICAL FORM**

Pink circular coated tablets.

Film-coated tablets.

### **4. PACKAGE SIZE**

Each box contains 5 blister strips of ten tablets.

### **5. TARGET SPECIES**

Cats and dogs.

### **6. INDICATIONS**

For the treatment of periodontal and related oral conditions in dogs and cats. Metronidazole has antimicrobial activity against most anaerobes, including *Bacteroides*, *Fusobacterium* and spirochaetes. Spiramycin has a therapeutic spectrum including Gram-positive aerobes such as staphylococci, streptococci and *Bacillus*, but also including anaerobes such as *Actinomyces*, *Clostridium* and *Bacteroides*. Antimicrobial synergy has been shown *in vitro* for many of these organisms.

### **7. METHOD AND ROUTES OF ADMINISTRATION**

#### **Dosage and administration**

By oral administration.

For dogs and cats, 23.4 mg spiramycin and 12.5 mg metronidazole/kg bodyweight, equivalent to 1 tablet/10 kg bodyweight, once daily for 5 to 10 days.

### **8. WITHDRAWAL PERIOD**

## **9. SPECIAL WARNINGS, IF NECESSARY**

STOMORGYL 2 may be more suitable for cats.

### **Contra-indications and adverse reactions**

Do not use in animals with a known hypersensitivity to spiramycin or metronidazole.

The tablets should not be crushed or divided.

### **Overdose**

No signs of toxicity were seen in cats receiving 5 times the recommended dose, or dogs receiving 8 times the recommended dose.

### **Standard operator warnings**

Wash hands after use.

In case of accidental ingestion obtain medical advice if needed.

Should direct skin contact occur wash affected area.

Should accidental eye exposure occur flush eyes immediately with water and seek medical attention if needed.

### **Precautions**

Check expiry date before use.

### **Further information**

STOMORGYL should not be used concurrently with other antibiotics of the macrolide group.

Safety in pregnant dogs and cats has not been demonstrated.

## **10. EXPIRY DATE**

Expiry:

## **11. SPECIAL STORAGE CONDITIONS**

### **Special storage precautions**

Do not store above 25°C.

Store in a dry place. Protect from light.

Keep the blister packs in the outer carton.

## **12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

### **Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE** *[Distribution category]*

For animal treatment only.

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| POM-V |
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## **14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

## **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

### **Manufacturer responsible for batch release:**

Boehringer Ingelheim Animal Health France SCS, 4 Chemin du Calquet,  
31000 Toulouse, France

### **Marketing authorisation holder:**

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

## **16. MARKETING AUTHORISATION NUMBER(S)**

Vm 08327/4084

## **17. MANUFACTURER'S BATCH NUMBER**

Batch no.:

## **18. ADDITIONAL INFORMATION**

To be supplied only on veterinary prescription.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS (Blister foil)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Stomorgyl 10

Tablets

Spiramycin and Metronidazole

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Boehringer Ingelheim

**3. EXPIRY DATE**

Exp.:

**4. BATCH NUMBER**

Batch:

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

Approved 28 May 2020

A handwritten signature in black ink, appearing to read 'A. Hunter.', is positioned below the approval date.