PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Stomorgyl 20 Film-coated Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 469 mg spiramycin of standard potency (3,200 IU/mg), and 250 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. INDICATION(S)

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/20 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.
Digestive tract disorders (vomitus, diarrhoea, anorexia) may occur very rarely (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

POM-V

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 Limited, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/5066

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 20
Tablets
Spiramycin and Metronidazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

3. EXPIRY DATE

Exp.:

4. BATCH NUMBER

Batch:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Gavin Hall
Approved: 28 August 2025