SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STOMORGYL 2
Film-coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Spiramycin	150,000 IU
Metronidazole	25mg
Colorants: Ponceau 4R	0.06mg
Titanium dioxide E171	0.20mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet. Pink circular convex scored tablet.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use (specifying the target species)

For the treatment of periodontal and related oral conditions in dogs and cats.

4.3 Contraindications

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

4.4 Special warnings (for each target species)

None.

4.5 Special precautions for use

i. Special precautions for use in animals

None.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to the animals

In case of accidental ingestion obtain medical advice if needed. Wash hands after use. Should direct skin contact occur, wash affected area. Should accidental eye exposure occur, flush the eyes immediately with water and

seek medical attention if needed.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Safety in pregnant dogs and cats has not been demonstrated.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amount(s) to be administered and administration route

By oral administration. For dogs and cats, 23.4 mg spiramycin and 12.5 mg metronidazole/kg bodyweight, once daily for 5 to 10 days.

Equivalent to: 1 tablet/2 kg bodyweight once daily for 5-10 days.
Do not break or crush the tablets.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Antibacterials for systemic use, combinations of antibacterials

ATCVet code: QJ01RA04

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Oxide, hydrated
Sorbitol
Dextrin, white
Gelatin
Citric Acid Monohydrate
Magnesium Stearate
Wheat Starch
Film coating:
Ponceau 4R (E124)
Titanium Dioxide (E171)
Hypromellose 6 m Pa s
Polyethylene Glycol 20000

6.2 Major incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^0C. Store in a dry place. Protect from light.

6.5 Nature and composition of immediate packaging

Opaque, white, non-plasticised polyvinylchloride-acetochloride blister pack with aluminium foil backing containing 10 tablets per strip. Each box contains five blister strips.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4083

9. DATE OF FIRST AUTHORISATION

30 June 1993

10. DATE OF REVISION OF THE TEXT

November 2018

ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE

Not applicable

Approved 01 November 2018