Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 480 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Trimethoprim	80 mg
Sulfadiazine	400 mg

Excipients:
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
An off-white circular tablet scored on one side.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

In vitro, Norodine is effective against most common Gram-positive and Gram-negative bacteria including *Escherichia coli*, *Klebsiella pneumonia, Pasteurella multocida, Streptococcus* spp., *Staphylococcus* spp., *Salmonella* spp., *Corynebacterium* spp. *Proteus mirabilis* and *Citrobacter freundii.*

When susceptible organisms are present, Norodine 480 mg Tablets are indicated for oral use in dogs for the treatment of alimentary tract infections, respiratory and urogenital infections, skin and wound infections and eye and ear infections.

4.3 Contraindications

Do not use in cats. Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special Precautions to be taken by the Person Administering the Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

A low incidence of polyarthropathy and Keratoconjunctivitis Sicca (Dry Eye) has been reported in dogs following oral administration of potentiated sulfonamides. If either of these conditions occur, it is recommended that medication is stopped and that future treatment is avoided.

4.7 Use during pregnancy, lactation or lay

Norodine 480 mg Tablets can be safely administered during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

The daily dose is one tablet per 16 kg bodyweight administered orally, providing 30 mg of combined active ingredients per kg bodyweight. Treatment should be continued until two days after the clinical signs have resolved up to a maximum of five days.

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

Not applicable.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, sulfonamides and trimethoprim
ATCvet Code: QJ01EW10

5.1 Pharmacodynamic properties

Sulfadiazine (SDZ) inhibits the incorporation of para-aminobenzoic acid into folic acid and trimethoprim (TMP) inhibits the enzyme dihydrofolate reductase (DHFR) which converts dihydrofolic acid into tetrahydrofolic acid. TMP and SDZ act together synergistically with a double-blockage mode of action. The combination is bactericidal inhibiting sequential steps in the synthesis of purines which are required for DNA synthesis. TMP-SDZ combinations have a broad and bactericidal action against many gram-positive and gram-negative aerobic bacteria, a large proportion of anaerobic bacteria, chlamydia and protozoa.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose microcrystalline Povidone (K30)
Lactose Monohydrate
Sodium Starch Glycollate Magnesium Stearate

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Store below 25ºC.
Protect from light.
Store in a dry place.

6.5 Nature and composition of immediate packaging

Tablets are stored in white polypropylene securitubs sealed with a white polyethylene cap. The tablets are packaged in quantities of 100 and 500 tablets. Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/017/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

January 2019