

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norodine 20 Coated Tablets

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

#### Active Substance:

Each tablet contains:  
Trimethoprim 20mg  
Sulfadiazine 100 mg.

#### Excipients:

Titanium dioxide (E171) 0.27mg.  
For a full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Coated tablet.  
An off white, sugar coated, unscored, circular tablet.

### 4. CLINICAL PARTICULARS

#### 4.1 Target species

Dogs  
Adult Cats

#### 4.2 Indications for use, specifying the target species

Alimentary tract infections, respiratory and urogenital infections, skin and wound infections, and eye and ear infections where susceptible organisms are present

#### 4.3 Contraindications

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

#### 4.3 Special Warnings for each target species

None

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

The tablets should not be divided.

When given to cats the tablets should not be crushed before administration.

Maintain adequate fluid intake during treatment.

Not to be used in cases of hepatic renal impairment or blood dyscrasia

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

##### **Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Take care to avoid skin contact. Wash hands after use.

Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to sulphonamides may lead to cross reactions with other antibiotics. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitive to sulphonamides.
2. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning.

#### **4.6 Adverse reactions (frequency and seriousness)**

Sulphonamide sensitivity is rare in companion animals but should be considered in cases of unexpected responses to treatment.

#### **4.7 Use during pregnancy, lactation or lay**

Norodine 20 Tablets can be safely administered during pregnancy and lactation.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

No known interactions.

#### **4.9 Amounts to be administered and administration route**

Administer orally by hand.

The daily dose is 30 mg of combined active ingredient per kg bodyweight. This is achieved using the following doses:

Dogs and Adult Cats: 1 tablet per 4 kg bodyweight.

Treatment should be continued for up to 5 days or until 2 days after symptoms have subsided

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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

No data available

#### **4.11 Withdrawal period**

Not applicable

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Sulphonamides

**ATC Vet 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-blockade 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 bactericidal action against many gram-positive and gram-negative aerobic bacteria and a large proportion of anaerobic bacteria.

Sulphonamides are absorbed rapidly after oral administration and diffuse rapidly into tissues. Elimination is mainly by metabolism in the liver and excretion in the urine. Trimethoprim also diffuses well into body tissues and though eliminated quicker, the combination remains active for sufficient time to achieve effective antimicrobial activity.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Titanium Dioxide (E171)  
Cellulose Microcrystalline  
Lactose Monohydrate  
Sodium starch Glycollate  
Povidone (K17)  
Magnesium Stearate  
Sucrose  
Talc Purified

### **6.2 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**

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

### **6.5 Nature and composition of immediate packaging**

White polypropylene securitubs sealed with a white, low density, push fit, tamper evident polyethylene cap containing 100 tablets.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

Norbrook Laboratories Limited  
Station Works,  
Camlough Road  
NEWRY  
Co. Down, BT35 6JP  
Northern Ireland

**8. MARKETING AUTHORISATION NUMBER(S)**

Vm 02000/4096

**9. DATE OF FIRST AUTHORISATION**

20<sup>th</sup> November 1987

**10. DATE OF REVISION OF THE TEXT**

November 2008