

## **PARTICULARS TO APPEAR ON LABEL**

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

Trimacare 20 Tablets

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

Each Tablet contains:

Trimethoprim	20 mg
Sulphadiazine	100 mg

### **3. PHARMACEUTICAL FORM**

Off-white, sugar-coated, unscored, circular tablets

### **4. PACKAGE SIZE**

100 Tablets

### **5. TARGET SPECIES**

Dogs

Adult Cats

### **6. INDICATION(S)**

When susceptible organisms are present the combination may be effective in treating alimentary tract infections, respiratory and urogenital infections, skin and wound infections, and eye and ear infections where susceptible organisms are present.

### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For oral administration to dogs and adult cats.

Dogs: 1 Tablet per 4 kg bodyweight,

Adult cats: 1 Tablet

Dose once daily for 5 consecutive days, or until 2 days after symptoms have subsided.

### **8. WITHDRAWAL PERIOD**

Not Applicable

### **9. SPECIAL WARNING(S), IF NECESSARY**

When given to cats the tablet should not be broken, chipped or halved.

Wash hands after use.

SULHONAMIDES may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

#### **10. EXPIRY DATE**

Exp.: dd/mm/yy

#### **11. SPECIAL STORAGE CONDITIONS**

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

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

#### **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
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 To be supplied only on veterinary prescription

#### **14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

**Keep out of the reach and sight of children.**

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

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

ManA:2000

Vm: 02000/4146

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

Bn.:  
D.O.M.:

**Further Information:**  
See package insert.

**Distributed by:**  
Animalcare Ltd  
10 Great North Way  
York  
YO26 6RB

**[Include information under these headings as it appears in the SPC]**

**PACKAGE LEAFLET FOR:**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Norbrook Laboratories Limited  
Station Works  
Newry  
Co. Down, BT35 6JP  
Northern Ireland

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

Trimacare 20 Tablets

**3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

Off-white, sugar-coated, unscored, circular tablets. Each tablet contains:

Trimethoprim	20 mg
Sulphadiazine	100 mg

**4. INDICATION(S)**

Trimacare 20 Tablets are indicated for oral use in dogs and adult cats. Together the active ingredients produce a double blockade of folic acid synthesis in bacteria, resulting in a level of activity much greater than that obtained from either drug alone. *In vitro*, Trimacare is effective against most common Gram-positive and Gram-negative bacteria including *Escherichia coli*, *Klebsiella pneumonia*, *Pasteurella* spp, *Streptococcus* spp, *Staphylococcus* spp, *Salmonella* spp, *Corynebacterium* spp, *Proteus mirabilis* and *Citrobacter freundii*.

When susceptible organisms are present Trimacare 20 Tablets may be effective in treating the following conditions: alimentary tract infections; respiratory and urogenital infections; skin and wound infections; eye and ear infections.

**5. CONTRAINDICATIONS**

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

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 occur it is recommended that medication is stopped and that future treatment with similar products is avoided.

## **6. ADVERSE REACTIONS**

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Dogs

Adult Cats

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

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

Dogs, and adult cats: One tablet per 4 kg bodyweight daily.

Treatment should be continued for up to five days or until two days after symptoms have subsided.

## **9. ADVICE ON CORRECT ADMINISTRATION**

This product should be administered orally by hand.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight of children.

Store in a dry place.

Do not store above 25°C.

Protect from light.

## **12. SPECIAL WARNING(S)**

Take care to avoid skin contact.

Wash hands after use.

Sulphonamides may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hyper sensitivity 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 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.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

**Legal Category:**

POM-V To be supplied only on veterinary prescription.

**Package Quantities:**

Plastic containers of 100 tablets.

**Product Licence Number:**

Vm 02000/4146

**Distributed by:**

Animalcare Ltd  
10 Great North Way  
York  
YO26 6RB

FOR ANIMAL TREATMENT ONLY

**Approved: 15/06/2017**

