

## **PARTICULARS TO APPEAR ON LABEL**

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

Trimacare Tablet Bolus

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

Each tablet contains:

Trimethoprim.	200 mg
Sulphadiazine	1.0 mg

### **3. PHARMACEUTICAL FORM**

Tablet

### **4. PACKAGE SIZE**

20/50 Tablets

### **5. TARGET SPECIES**

Calves

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

The product is indicated primarily for the treatment of bacterial scours but may also be used for the treatment of acute salmonellosis and bacterial pneumonia.

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

1 tablet per 40kg bodyweight given orally. Repeat daily until 2 days after the symptoms have resolved, but in cases of salmonellosis and bacterial pneumonia treatment should be continued for 5 consecutive days, but no longer. Trimacare tablets may be administered whole, by hand or by balling gun, or dispersed in water.

Dosage by dispersion in water:

Disperse each tablet by shaking in about 300ml of water in a dosing bottle. This may be facilitated by crushing the tablet before placing it in the bottle. After dosing by this method any unused material should be discarded.

### **8. WITHDRAWAL PERIOD**

Animals must not be slaughtered for human consumption during treatment.

Calves may be slaughtered for human consumption only after 15 days from the last treatment.

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

Trimacare Tablet should not be used in animals with functionally mature rumens.

Protective gloves should be worn whilst handling this product.

Wash hands and exposed skin after use.

SULPHONAMIDES 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: 02000/4148

**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 Tablet Bolus

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

Scored white bolus-shaped tablets.

Each tablet contains:

Trimethoprim	200 mg
Sulphadiazine	1.0 g

**4. INDICATION(S)**

Trimacare Tablets are primarily indicated for oral use in calves for the treatment of bacterial scours but may also be used for the treatment of acute salmonellosis and bacterial pneumonia. Together the active ingredients produce a double blockade of folic acid synthesis in bacteria giving a level of activity many times greater than that obtained from either drug alone. *In vitro* Trimacare Tablets are effective against most common Gram-positive and Gram-negative bacteria including *Escherichia coli*, *Klebsiella* spp, *Pasteurella* spp, *Salmonella* spp, and *Staphylococcus* spp.

The tablets are particularly effective against *Escherichia coli* and *Salmonella* spp infections.

**5. CONTRAINDICATIONS**

Not to be administered to animals with functionally mature rumens.

## **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**

Calves

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

The daily dose is one tablet per 40 kg (90 lb) bodyweight given orally, providing 30 mg of combined active constituents per kg bodyweight daily.

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 (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Treatment should be repeated daily until two days after the symptoms have resolved, but in cases of salmonellosis and bacterial pneumonia treatment should be continued for five consecutive days. Treatment must not be continued for more than five days.

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

Trimacare Tablets may be administered whole, by hand or by balling gun, or dispersed in water.

Dosage by dispersion in water: Disperse each tablet by shaking in about 300 ml of water in a dosing bottle. This may be facilitated by crushing the tablet before placing it in the bottle. After dosing by this method any unused material should be discarded

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

Calves: meat – 15 days

Animals must not be slaughtered for human consumption during treatment.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight of children.

Do not store above 25°C.

Store in a dry place.

Protect from light.

For animal treatment only.

## 12. SPECIAL WARNING(S)

Take care to avoid skin and eye contact. Protective gloves should be worn whilst handling this product. Wash hands and exposed skin 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 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.

Wash hands after use.

## 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

**POM-V** To be supplied only on veterinary prescription

### **Package Quantities:**

Plastic tubs containing 20 or 50 tablets.

### **Marketing Authorisation Number:**

Vm 02000/4148

### **Distributed By:**

Animalcare Ltd  
10 Great North Way  
York  
YO26 6RB

**Approved: 15/06/2017**

