

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimacare 80 Tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each Tablet contains:

Trimethoprim 80 mg

Sulphadiazine 400 mg

3. PHARMACEUTICAL FORM

White circular uncoated tablets scored on one side

4. PACKAGE SIZE

100/500 Tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Trimacare 80 Tablets are indicated for oral use in dogs. 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 multocida*, *Streptococcus* spp, *Staphylococcus* spp, *Salmonella* spp, *Corynebacterium* spp, *Proteus mirabilis* and *Citrobacter freundii*.

When susceptible organisms are present Trimacare 80 Tablets may be effective in treating the following conditions: alimentary tract infections; respiratory and urogenital infections; skin and wound infections; eye and ear infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration to dogs.

1 tablet per 16 kg bodyweight.

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

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

This dosage form is not suitable for use in cats. Trimacare 20 Tablets should be administered to this species.

Wash hands 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 container 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

For Animal Treatment Only.

POM-V

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

Norbrook Laboratories Limited

Station Works

Newry

Co. Down, BT35 6JP

Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA: 2000

Vm: 02000/4147

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

PACKAGE LEAFLET FOR: Trimacare 80 Tablets

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 80 Tablets

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

White circular uncoated tablets scored on one side Each tablet contains:

Trimethoprim 80 mg

Sulphadiazine 400 mg

4. INDICATION(S)

Trimacare 80 Tablets are indicated for oral use in dogs. 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 multocida*, *Streptococcus* spp, *Staphylococcus* spp, *Salmonella* spp, *Corynebacterium* spp, *Proteus mirabilis* and *Citrobacter freundii*.

When susceptible organisms are present Trimacare 80 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

This dosage form is not suitable for use in cats. Trimacare 20 Tablets should be administered to this species.

6. ADVERSE REACTIONS

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

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

7. TARGET SPECIES

Dogs

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

The daily dose is one tablet per 16 kg bodyweight given orally, providing 30 mg of combined active ingredients per kg bodyweight. 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.

Do not store above 25°C.

Store in a dry place.

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. 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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2013

15. OTHER INFORMATION

Not all package sizes may be marketed.

Pack Sizes of 100 or 500 tablets

Further Information:

This product may be used to continue treatment commenced with Trimacare 24%.

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10 Great North Way

York

YO26 6RB

FOR ANIMAL TREATMENT ONLY

POM-V

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Approved: 07/09/2017

