PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trimacare 24 % w/v solution for injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Sulfadiazine. 20%w/v
Trimethoprim 4%w/v

Sulfadiazine 200 mg/ml
Trimethoprim 40 mg/ml

Chlorocresol (preservative) 0.1%w/v and sodium formaldehyde 0.1%w/v sulphoxylate 1 mg in an aqueous solution

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 / 100ml

5. TARGET SPECIES

Horses
Cattle
Pigs
Dogs
Cats

6. INDICATION(S)

To be used in the treatment of acute, subacute and chronic conditions of bacterial origin in horses, cattle, pigs, dogs and cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In cattle and pigs administer by intramuscular or slow intravenous injection at a rate of 1 ml/16 kg bodyweight.
In horses administer at a rate of 1 ml/16 kg by slow intravenous injection only.
In dogs and cats administer at a rate of 1 ml/8 kg by subcutaneous injection only.

8. WITHDRAWAL PERIOD

Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may only be taken after 48 hours from the last treatment.
Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 12 days from the last treatment. Pigs may be slaughtered for human consumption only after 20 days from the last treatment.
Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Injections should not be given by routes other than those recommended.
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

User Warnings: Care should be taken to avoid accidental self-injection.

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

10. EXPIRY DATE

Exp.: dd/mm/yy
Discard by:_____

11. SPECIAL STORAGE CONDITIONS

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
Do not store above 25ºC.
Do not freeze.
Protect from light.
Crystallisation of the product at low temperatures can be reversed by gentle warming.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

ManA: 2000
Vm 02000/4145

17. MANUFACTURER'S BATCH NUMBER

Bn.:
D.O.M.:

Distributed by:

Animalcare Ltd
10 Great North Way
York
YO26 6RB

Further Information: See Package Insert.

PACKAGE LEAFLET FOR:

Trimacare 24 % w/v solution for injection.

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 24%w/v solution for injection.

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

A clear yellow aqueous solution for parenteral administration containing as active ingredients per ml sulfadiazine 20%w/v and trimethoprim 4%w/v.
Preservative: Chlorocresol 0.1%w/v and sodium formaldehyde sulphoxylate 0.1%w/v

4. INDICATION(S)

Trimacare 24% is indicated in the treatment of acute, subacute and chronic conditions of bacterial origin in horses, cattle, pigs, dogs and cats. The therapeutic spectrum includes both Gram-negative and Gram-positive bacteria including Streptococci, Staphylococci, Actinobacilli, Actinomycae, Salmonella, Pasteurella, Pneumococci, Proteus, *E. coli,* Corynebacteria, Vibrio, Bordetella, Brucella, Klebsiellae and Haemophilae. It is also indicated in species where there may be an existing antibiotic drug resistance. Trimacare 24% may be administered in respiratory infections of bacterial origin including rhinitis, pneumonia, bronchitis and in bacterial infections secondary to viral disease such as viral pneumonia or mycoplasma infections. It is also indicated in urogenital tract infections (cystitis, vaginitis, urethritis, nephritis and metritis) and alimentary tract infections (including neonatal diarrhoea and salmonellosis). Other infections include foul-in-the-foot, severe mastitis, bacterial agalactia of sows, and infections of eye, ear and mouth.

Use of this 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.

5. CONTRAINDICATIONS

Trimacare 24% should not be given by routes other than those recommended. Not to be administered intraperitoneally.

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

Horses
Cattle
Pigs
Dogs
Cats

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

For cattle and pigs the dose is 1 ml per 16 kg bodyweight daily by intramuscular or slow intravenous injection.

Trimacare 24% may be administered by intravenous injection when rapid blood levels of sulfadiazine and trimethoprim are required.

For horses the dose is 1 ml per 16 kg bodyweight by slow intravenous injection only.

For dogs and cats the dose is 1 ml per 8 kg bodyweight, by subcutaneous injection only. The recommended site in dogs is the loose skin at the top of the neck.

9. ADVICE ON CORRECT ADMINISTRATION

A single injection may be sufficient in uncomplicated conditions, but in severe infections they may be repeated daily until two days after the symptoms resolve, up to a maximum of five days.

An appropriate graduated syringe must be used to allow accurate administration of the required volume. This is particularly important when injecting small volumes into small animals.

Adequate drinking water should be available during the therapeutic effect of the product.

10. WITHDRAWAL PERIOD(S)

Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may only be taken after 48 hours from the last treatment.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 12 days from the last treatment. Pigs may be slaughtered for human consumption only after 20 days from the last treatment.

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store below 25ºC.
Do not freeze.
Crystallization of the product at low temperatures can be reversed by gentle warming.
Protect from light.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
When the container is broached for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Trimacare 24% is contraindicated in animals with known sulphonamide sensitivity, severe liver parenchymal damage, or blood dyscrasias.

Do not administer to horses exhibiting drug-induced cardiac arrhythmias. Such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents.

Anaphylactic shock, potentially fatal, has been observed on rare occasions following administration of potentiated sulphonamide preparations, particularly by the intravenous route. Veterinary surgeons should be mindful of this possibility during the injection process. For intravenous administration the product should be warmed to body temperature and injected slowly over as long a period as is reasonably practical. At the first sign of intolerance the injection should be interrupted and shock treatment initiated.

Care must be taken to avoid accidental injection and contact with the skin. 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 containers 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

Package Quantities
Multidose vials of 50 ml and 100 ml.

Marketing Authorisation Number
Vm: 02000/4145
ManA: 2000

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

FOR ANIMAL TREATMENT ONLY.

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Approved: 07/07/2017