

Trimacare 24% Solution for Injection

Introduction



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Presentation

A clear yellow aqueous solution for parenteral administration containing as active ingredients per ml Sulfadiazine 200 mg and Trimethoprim 40 mg.

Preservative: Chlorocresol 1 mg/ml.

Antioxidant: Sodium Formaldehyde Sulphoxylate dihydrate 1 mg/ml

Uses

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 9890-Gram-positive bacteria including *Streptococci*, *Actinobacilli*, *Actinomycaea*, *Salmonella*, *Staphylococci*, *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.

Dosage and administration

For cattle and pigs the dose is 1 ml per 16kg 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.

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.

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 appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

Contra-indications, warnings, etc

Injections should not be given by routes other than those recommended. Not to be administered intraperitoneally.

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

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.

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

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.

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

Potentially fatal anaphylactic shock 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 self-injection.

Pharmaceutical precautions

Store below 25°C. Do not freeze. Crystalization of the product at low temperatures can be reversed by gentle warming. Protect from light. Keep out of the reach of children.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

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

When the container is broached for the first time, using the in-use shelf-life which is specified on the 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.

Legal category

POM-V

Packaging Quantities

Multidose Vials of 100 ml.

Further information

Nil

Marketing Authorisation Holder (if different from distributor)

Norbrook Laboratories Ltd, Northern Ireland

Marketing authorisation number

Vm 2000/4145.

GTIN (Global Trade Item No)

100ml Vial:

05055037400434