

Streptacare Suspension for Injection

Introduction



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Presentation

A white to off-white aqueous suspension for parenteral administration. Each ml contains:

Procaine Penicillin/Procaine Benzylpenicillin	200 mg
Dihydrostreptomycin Sulphate	250 mg
Preservatives:	.
Methyl Hydroxybenzoate	0.107% w/v
Ethyl Hydroxybenzoate	0.025% w/v
Propyl Hydroxybenzoate	0.0145% w/v
Sodium formaldehyde sulphoxylate dihydrate	0.125% w/v

Uses

Streptacare is indicated for use in cattle, horses, pigs and sheep for the treatment of infections caused by, or associated with, organisms sensitive to Penicillin and/or Streptomycin including:

Corynebacterium pyogenes, *Erysipelothrix rhusiopathiae*, *Klebsiella pneumoniae*, *Listeria* spp., *Pasteurella haemolytica*, *Pasteurella multocida*, *Staphylococcus* spp., *Streptococcus* spp., and *Salmonella* spp.

Streptacare will therefore be effective in the treatment of infections caused by susceptible organisms including:

erysipelas; navel/joint ill; respiratory tract infections including pneumonia and atrophic rhinitis; listeriosis; meningitis; septicaemia; toxæmia associated with mastitis; urogenital tract infections; enteritis associated with *Salmonella* spp., salmonellosis; and the control of secondary bacterial invaders in diseases of primary viral origin.

The combination of penicillin and dihydrostreptomycin is especially useful in the treatment of mixed infections involving both Gram-positive and Gram-negative organisms.

Dosage and administration

The recommended daily dose for cattle, horses, pigs and sheep is 8 mg procaine penicillin and 10 mg dihydrostreptomycin sulphate per kg bodyweight achieved by administering 1 ml Streptacare per 25 kg bodyweight. The dose should be given once daily by deep intramuscular injection for up to three consecutive days. The maximum dose volume administered at one site should not exceed 15 ml for horses, 6 ml for cattle, 3 ml for sheep and 1.5 ml for pigs.

Contra-indications, warnings, etc

Contra-indications in known cases of hypersensitivity to penicillins. Occasionally in suckling and fattening pigs administration of this product may cause a transient pyrexia, vomiting, shivering, listlessness and inco-ordination. Additionally in pregnant sows and gilts, a vulval discharge which could be associated with abortion, has been reported. A palpable but transient local reaction may occur at the site of intramuscular administration in horses. Care should be taken not to exceed the recommended dosage.

Withdrawal Periods

Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cows after 60 hours from the last treatment.

Not intended for use in sheep producing milk for human consumption.

Animals must not be slaughtered for human consumption during treatment.

Cattle intended for human consumption should not be slaughtered until 23 days after the last treatment.

Pigs intended for human consumption should not be slaughtered until 18 days after the last treatment. Sheep intended for human consumption should not be slaughtered until 31 days after 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.

Operator warning-Penicillin/Cephalosporin sensitivity

Penicillins and cephalosporins may cause sensitisation following injection, inhalation, ingestion or skin contact. Sensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure taking all recommended precautions.
3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require *urgent* medical attention.
4. Wash hands after use.

Care should be taken to avoid accidental self injection.

Pharmaceutical precautions

Shake the container before use.

Do not store above 25°C

Protect from light

Keep out of reach of children

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

Legal category

POM-V

Packaging Quantities

Multidose vials of 100 ml

Disposal

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

Further information

When the container is breached (opened) 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.

Marketing Authorisation Holder (if different from distributor)

Norbrook Laboratories Ltd, Northern Ireland

Marketing authorisation number

Vm 2000/4155.

GTIN (Global Trade Item No)

100ml Vial:

05055037400397