PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE

50/100ML GLASS VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Streptacare Suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains

Procaine Penicillin 200 mg

Dihydrostreptomycin Sulphate 250 mg

and 1.5 mg Hydroxybenzoate Esters (as Nipasept sodium) as antimicrobial preservative and 1.25 mg sodium formaldehyde sulphoxylate dihydrate as antioxidant.

3. PHARMACEUTICAL FORM

Suspension for injection.

A white to off-white suspension

4. PACKAGE SIZE

50/100ml

5. TARGET SPECIES

Cattle, Horses, Sheep, Pigs

6. INDICATION(S)

For the treatment of infections in cattle, horses, pigs and sheep caused by, or associated with organisms sensitive to penicillin and/or streptomycin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For deep intramuscular injection.

Shake the vial before use

Recommended dose rate: 1 ml per 25 kg bodyweight for up to three consecutive days. The maximum volume injected per administration site should not exceed 15 ml for horses, 6 ml for cattle, 3 ml for sheep and 1.5 ml for pigs.

8. WITHDRAWAL PERIOD

Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cattle 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.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillin/Cephalosporin may occasionally cause severe allergic reactions. See package leaflet for operator warning.

In rare cases, hypersensitivity reactions can occur and very rarely, these can be fatal. Very rarely, in sucking and fattening pigs, administration of this product may cause a transient pyrexia, vomiting, shivering, listlessness and in co-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.

10. EXPIRY DATE

D.O.M:

Exp.: dd/mm/yy

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

DATE OF FIRST BROACHING: __/__/__

DATE TO DISCARD: __/__/__

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

Protect from light.

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Discard unused material. 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 by veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach 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 02000/4155

17. MANUFACTURER'S BATCH NUMBER

Bn.:

Further information: See Package Insert.

Distributed by:

Animalcare Limited
10 Great North Way
York
YO26 6RB

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE

50/100/250ML PLASTIC VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Streptacare Suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains

Procaine Penicillin 200 mg

Dihydrostreptomycin Sulphate 250 mg

and 1.5 mg Hydroxybenzoate Esters (as Nipasept sodium) as antimicrobial preservative and 1.25 mg sodium formaldehyde sulphoxylate dihydrate as antioxidant.

3. PHARMACEUTICAL FORM

Suspension for injection.

A white to off-white suspension

4. PACKAGE SIZE

50, 100 ml and 250 ml plastic vials

5. TARGET SPECIES

Cattle, Horses, Sheep, Pigs

6. INDICATION(S)

For the treatment of infections in cattle, horses, pigs and sheep caused by, or associated with organisms sensitive to penicillin and/or streptomycin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For deep intramuscular injection.

Shake the vial before use

Recommended dose rate: 1 ml per 25 kg bodyweight for up to three consecutive days. The maximum volume injected per administration site should not exceed 15 ml for horses, 6 ml for cattle, 3 ml for sheep and 1.5 ml for pigs.

8. WITHDRAWAL PERIOD

Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cattle 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.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillin/Cephalosporin may occasionally cause severe allergic reactions. See package leaflet for operator warning.

In rare cases, hypersensitivity reactions can occur and very rarely, these can be fatal. Very rarely, in sucking and fattening pigs, administration of this product may cause a transient pyrexia, vomiting, shivering, listlessness and in co-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.

10. EXPIRY DATE

D.O.M:

Exp.: dd/mm/yy

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

DATE OF FIRST BROACHING: __/__/__

DATE TO DISCARD: __/__/__

11. SPECIAL STORAGE CONDITIONS

Store between 2 – 8^{o}C.

Protect from light.

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Discard unused material. 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 by veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach 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 02000/4155

17. MANUFACTURER'S BATCH NUMBER

Bn.:

Further information: See Package Insert.

Distributed by:

Animalcare Limited

10 Great North Way

York

YO26 6RB

PACKAGE LEAFLET FOR: STREPTACARE SUSPENSION FOR INJECTION

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Manufactured by:

Norbrook Laboratories Limited

Station Works

Newry

Co Down

BT35 6JP

Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Streptacare Suspension for injection.

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

A white to off-white suspension for parenteral administration.

Each ml contains

Procaine Penicillin 200 mg

Dihydrostreptomycin Sulphate 250 mg

and 1.5 mg Hydroxybenzoate Esters (as Nipasept sodium) [as antimicrobial preservativesmethyl parahydroxybenzoate1.07 mg*, ethyl parahydroxybenzoate 0.25 mg*, propyl parahydroxybenzoate 0.145 mg* (* as approximate amounts)]

and 1.25 mg sodium formaldehyde sulphoxylate dihydrate as antioxidant.

4. INDICATION(S)

Streptacare Injection 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:

Arcanobacterium pyogenes, Erysipelothrix rhusiopathiae, Klebsiella pneumonia, Listeria spp, *Mannheimia 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; toxaemia 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.

5. CONTRAINDICATIONS

Contraindicated in known cases of hypersensitivity to penicillins.

6. ADVERSE REACTIONS

In rare cases, hypersensitivity reactions can occur and very rarely, these can be fatal. Very rarely, in sucking and fattening pigs, administration may cause a transient pyrexia, vomiting, shivering, listlessness and in-coordination. A palpable but transient local reaction may occur at the site of intramuscular administration in horses. Additionally in pregnant sows and gilts, a vulval discharge which could be associated with abortion has been reported.

The frequency of adverse reactions is defined using the following convention:
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, Horses, Sheep, Pigs

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

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial before use.

Care should be taken not to exceed the recommended dosage.

10. WITHDRAWAL PERIOD(S)

Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cattle 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Glass: Do not store above 25^{o}C

Plastic: Store between 2 – 8^{o}C

Protect from light.

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

When the container is broached (opened) 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)

Use with care in animals known to have kidney disease or defective renal function.

Do not exceed the recommended dosage or duration of treatment.

Do not administer with other antibiotics such as tetracyclines or with other aminoglycosides.

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately.

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 sensitivity to cephalosporins and vice versa. Allergic reactions to these substances are occasionally 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.

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

April 2022

<15. OTHER INFORMATION

Package Quantities:

Multidose glass vials of 50 ml and 100 ml, and plastic vials of 50 ml, 100 ml and 250 ml.

Not all pack sizes may be marketed

Marketing Authorisation Number

ManA: 2000

Vm 02000/4155

FOR ANIMAL TREATMENT ONLY.

POM-V

To be supplied only by veterinary prescription.

Distributed by:

Animalcare Ltd
10 Great North Way
York
YO26 6RB

Approved 04 April 2022