CARTON

PEN & STREP SUSPENSION FOR INJECTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PEN & STREP SUSPENSION FOR INJECTION

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A white to off-white aqueous 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 preservative and 1.25mg sodium formaldehyde sulphoxylate dihydrate as antioxidant.

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

50 ml and 100 ml glass vials
50 ml, 100 ml and 250 ml plastic vials

5. TARGET SPECIES

Cattle, Horses, Sheep, Pigs

6. INDICATION(S)

Pen & Strep 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.
Pen & Strep 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake the container before use.
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 Pen & Strep 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.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.
Sheep: Milk- Not to be used in sheep producing milk for human consumption. Meat- 31 days. **Cattle:** Milk- 60 hours. Milk for human consumption must not be taken during treatment. Meat- 23 days. **Pigs:** Meat- 18 days. **Horses:** 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

Contraindicated in known cases of hypersensitivity to penicillins. 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 incoordination. 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.

Operator Warning - Penicillin/Cephalosporin Sensitivity
Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.

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.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Store between 2 – 8ºC. Protect from light.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
Keep container in outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, if applicable

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 sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by:
Norbrook Laboratories Limited
Newry, BT35 6JP

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm: 02000/4100

17. MANUFACTURER'S BATCH NUMBER

B.N.:

LOGO

Revised: March 2024
AN: 02550/2023

LABEL

Pen & Strep Suspension for Injection

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pen & Strep 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 1.25mg sodium formaldehyde sulphoxylate dihydrate as antioxidant.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml and 100 ml glass vials
50 ml, 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

Animals must not be slaughtered for human consumption during treatment.
Sheep: Milk- Not to be used in sheep producing milk for human consumption. Meat- 31 days. **Cattle:** Milk- 60 hours. Milk for human consumption must not be taken during treatment. Meat- 23 days. **Pigs:** Meat- 18 days. **Horses:** 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 full operator warnings.

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 incoordination. 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

EXP:

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. Discard unused material.
Keep container in outer carton.

12. SPECIAL 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 sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufacturer:
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4100

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

DATE OF FIRST BROACHING: __/__/__
DATE TO DISCARD: __/__/__

Further information: See Package Leaflet.

PACKAGE LEAFLET

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

Norbrook Laboratories Limited
Newry, Co. Down
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pen & Strep Suspension for Injection

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

A white to off-white aqueous 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 preservative and 1.25mg sodium formaldehyde sulphoxylate dihydrate as antioxidant.

4. INDICATION(S)

Pen & Strep 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.

Pen & Strep 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 incoordination. 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.

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 Pen & Strep 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

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. Shake the container before use.
Care should be taken not to exceed the recommended dosage.

10. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.

Sheep:
Not to be used in sheep producing milk for human consumption.
Sheep intended for human consumption should not be slaughtered until 31 days after the last treatment.

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

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

Horses:
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

Store between 2 – 8^{o}C.
Protect from light.
Keep out of the sight and reach of children.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.
Keep container in outer carton.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNINGS

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 the 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 2024

15. OTHER INFORMATION

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

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.

BN:
D.O.M:
Exp:

ManA 2000
Vm 02000/4100

POM-V

To be supplied only on veterinary prescription

FOR ANIMAL TREATMENT ONLY
UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LOGO

Approved 23 April 2024