PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neopen suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Neomycin (as neomycin sulphate) 100 mg/ml and Procaine benzylpenicillin 200 mg/ml

3. PHARMACEUTICAL FORM

Aqueous suspension for injection (with 1.1 mg/ml methyl parahydroxybenzoate and 1.0 mg/ml sodium formaldehyde sulphoxylate anhydrous as antimicrobial preservatives) for the treatment of horses, sheep, pigs, dogs and cats.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, sheep, pigs, dogs and cats.

6. INDICATION(S)

Not applicable.

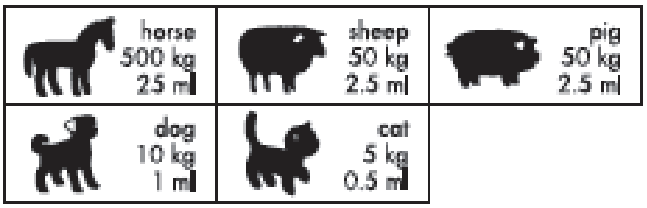
7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M.

To be used in accordance with the directions of a veterinary surgeon.

Shake container before use.

Wash hands after use.



8. WITHDRAWAL PERIOD

Meat withdrawal periods:

Pigs, 60 days, sheep 70 days.

Not to be used in sheep producing milk for human consumption or in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for further information, disposal advice and warnings before use.

Penicillins/cephalosporins may occasionally cause severe allergic reactions.

See package leaflet for user warning.

Not to be administered to animals known to be sensitive to penicillin.

10. EXPIRY DATE

Expiry end of:

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator at between +2 °C to +8 °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. 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

[Distribution category]

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 REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

Distributed in Northern Ireland by:

INTERVET IRELAND Ltd.

Magna Drive, Magna Business Park

Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4204

17. MANUFACTURER'S BATCH NUMBER

Batch No.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neopen suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Neomycin 100 mg/ml and Procaine benzylpenicillin 200 mg/ml

Also contains Methyl parahydroxybenzoate 1.1 mg/ml as preservative and Sodium formaldehyde sulphoxylate anhydrous 1.0 mg/ml as antioxidant.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

For the treatment of horses, sheep, pigs, dogs and cats.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M.

SHAKE CONTAINER BEFORE USE

<image placed as shown for user to be able to read when using the product>

8. WITHDRAWAL PERIOD

Withdrawal periods:

Meat: Pigs: 60 days; Sheep: 70 days.

Not to be used in sheep producing milk for human consumption. Not to be used in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for further information, disposal advice and warnings before use.

Penicillin/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warning.

10. EXPIRY DATE

Expiry end of:

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Store at between +2 °C to +8 °C.

Protect from light.

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

Discard unused material.

Observe aseptic precautions.

Keep container in outer carton.

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

Read package leaflet for further information, disposal advice and warnings before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

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 REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4204

17. MANUFACTURER'S BATCH NUMBER

Batch No.

PACKAGE LEAFLET FOR:

Neopen Suspension for injection

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

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

Buckinghamshire

MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neopen Suspension for injection

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

PRESENTATION

Neopen is an off-white suspension for injection of procaine benzylpenicillin in a solution of neomycin sulphate.

Each ml contains:

Neomycin base (as the sulplhate)	100 mg
Procaine benzylpenicillin (200,000 iu)	200 mg

Also contains Methyl parahydroxybenzoate 1.1 mg/ml as preservative and Sodium formaldehyde sulphoxylate anhydrous 1.0 mg/ml as antioxidant.

4. INDICATION(S)

USES

Penicillin is active against some Gram-negative and most Gram-positive bacteria. Neomycin is a broad spectrum antibiotic active against a number of Gram-positive and Gram-negative bacteria. The combination shows a broad spectrum of activity. For the treatment of infectious diseases in horses, sheep, pigs, dogs and cats caused by bacteria sensitive to the combination. In vitro activity has been demonstrated against all tested isolates of E. rhusiopathiae, Streptococcus spp and A. pyogenes and the majority of tested isolates of Pasteurella, Salmonella, Klebsiella and Staphylococcus spp.

5. CONTRAINDICATIONS

CONTRA-INDICATIONS, EARNINGS, ETC.

Overdosage with neomycin parenterally can cause renal damage and deafness, but this is unlikely at normal therapeutic dosage levels. Care should be taken in young animals, particularly puppies, kittens and piglets, to ensure accurate computation of dose.

Courses of Neopen should be restricted to a period of three days.

Occasionally 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. The balance of risks should be considered carefully prior to use.

Local reaction (swelling) may occur at the injection site in horses for up to a week after administration. Doses exceeding 15 ml should be divided between two injection sites.

6. ADVERSE REACTIONS

7. TARGET SPECIES

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

DOSAGE AND ADMINISTRATION

The following table is only intended as a guide and is calculated at a dosage rate of 5 mg/kg neomycin base (5 ml/100 kg) for large animals and 10 mg/kg (1 ml/10 kg) in small animals as representing the maximum dose.

Species	Weight	Maximum dose
Horse	500 kg	25 ml
Sheep	50 kg	2.5 ml
Pig	50 kg	2.5 ml
Dog	10 kg	1 ml
Cat	5 kg	0.5 ml

A suitably calibrated syringe should be used to ensure accurate injection of small volumes. Shake the container before use. The dose should be repeated at 24 hour intervals as required to a maximum of three doses.

Administration should be by deep intramuscular injection in all species. Observe aseptic precautions.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

WITHDRAWAL PERIODS

Pigs and sheep should not be slaughtered for human consumption during treatment. Pigs may only be slaughtered for human consumption from 60 days after the last treatment, sheep from 70 days after the last treatment.

Not to be used in sheep producing milk for human consumption.

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

PHARMACEUTICAL PRECAUTIONS

Store at between +2° to +8°C. Protect from light.

Shake the container before use. Following withdrawal of the first dose use the product within 28 days. Discard unused material. When the container is broached for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf life of the product is given on the package insert. The discard date should be written in the space provided on the label.

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

Keep container in outer carton.

12. SPECIAL WARNING(S)

USER WARNINGS

Care should be taken to avoid accidental self-injection.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may cause 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 with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

See Pharmaceutical Precautions section.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

15. OTHER INFORMATION

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

LEGAL CATEGORY

POM-V

To be supplied only on veterinary prescription.

PACKAGE QUANTITIES

Glass bottles or polyethylene terephthalate (PET) bottles containing 100 ml.

MARKETING AUTHORISATION NUMBER

Vm 01708/4204

MA Holder:

MSD Animal Health UK Ltd.

Walton Manor

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Distributed in Northern Ireland by:

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Magna Drive

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Dublin 24

Approved: 09/06/21