SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Neopen suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:

Neomycin (as neomycin sulphate)	100 mg
Procaine benzylpenicillin	200 mg

Excipients:

Methyl parahydroxybenzoate	1.1 mg
Sodium formaldehyde sulphoxylate anhydrous	1.0 mg

See section 6.1 for list of excipients

3. PHARMACEUTICAL FORM

Suspension for injection
White to cream coloured suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, sheep, pigs, dogs and cats

4.2 Indications for use, specifying the target species

For the treatment of infectious diseases in horses, sheep, pigs, dogs and cats caused by bacteria sensitive to the combination.

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. *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 species.

4.3 Contra-indications

Not to be used in animals known to be hypersensitive to Beta-lactam antibiotics.

4.4 Special warning for each target species

None known

4.5 Special precautions for use

(i) Special precautions for use in animals

See 4.3 above. Shake container before use.

(ii) Special precautions to be taken by the person administering the medicinal product to the animals

Care should be taken to avoid accidental self-injection.

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity 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.

4.6 Adverse reactions (frequency and seriousness)

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 this product 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.
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.

4.7 Use during pregnancy or lactation

The product is not contra-indicated, but see 4.6 above.
The balance of risks should be considered carefully prior to use.

4.8 Interaction with other medicinal products and other forms of interaction

Synergism occurs between beta-lactam antibiotics and amino-glycosides.
Penicillin exerts its bactericidal action by inhibition of bacterial call wall synthesis during multiplication. It is therefore in principle not compatible with bacteriostatic antibiotics (tetracyclines, chloramphenicol) which inhibit multiplication.

4.9 Amounts to be administered and administration route

Administration should be by deep intramuscular injection in all species. The dose should be repeated at 24 hour intervals as required to a maximum of three doses.
The following table is intended only as a guide and is calculated at a dosage rate of 5 mg/kg neomycin base (5 ml/100kg) for large animals and 10 mg/kg (1 ml/10 kg) in small animals as representing the maximum dose. Observe aseptic precautions.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No specific treatment or antidote recommended.

4.11 Withdrawal period(s)

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Penicillin is a bactericidal antibiotic of the beta-lactam class which acts by inhibition of bacterial cell wall synthesis. Neomycin belongs to the aminoglycoside class of antibiotics and acts by inhibition of protein synthesis by

interfering with ribosomal function.
Penicillin and neomycin have a broad spectrum of activity against both gram-positive and gram-negative bacteria and exhibit synergistic activity when used in combination.
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5.2 Pharmacokinetic particulars

Neomycin is not absorbed from the gastro-intestinal tract, and the absorption of procaine benzylpenicillin is poor.

After intramuscular administration both comounda are well resorbed. The distribution volume of both compounds is relatively low, but in the case of procaine benzylpenicillin the tissue penetration in inflamed tissues is increased. The main elimination pathway for both compounds is via the kidneys, mainly in the unchanged form.

Pharmacokinetics of procaine benzylpenicillin and neomycin after intramuscular administration are similar in equine, bovine, ovine and porcine species. Maximum blood levels of procaine benzylpenicillin (1 -2 I.U./ml) and neomycin (10-15 µg/ml) were achieved within hours and elimination is rapid. No accumulation occurs with a dosing interval of 24 hours.
In the dog, maximum benzylpenicillin levels of approximately 3 I.U/ml occur one to two hours after administration. Maximum neomycin levels occur slightly earlier and are higher and more variable than with large animals. In the cat the time at which maximum levels occurred were comparable to those observed in the dog. Maximum levels of benzylpenicillin were consistently higher in the cat, whereas neomycin concentrations obtained were comparable between the cat and dog.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Sodium formaldehyde sulphoxylate anhydrous
Lecithin
Mannitol
Povidone K30
Povidone K17
Citric acid monohydrate
Sodium citrate buffer pH7 (for pH adjustment)
Simeticone
Water for Injection

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Store at between +2° to +8°C. Protect from light.
Following withdrawal of the first dose use the product within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging

Ph.Eur. glass type II bottles containing 100 ml or PET, closed with nitryl rubber stoppers and sealed with aluminium caps.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4204

9. DATE OF FIRST AUTHORISATION

16 December 1992

10. DATE OF REVISION OF TEXT

June 2021

Approved: 09/06/21