Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Neopen Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances

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

Excipients

Methylparahydroxybenzoate (E218)	1.1 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs and horses

4.2 Indications for use, specifying the target species

For the treatment of infections caused by organisms which are susceptible to neomycin/penicillin combinations.

- In cattle and pigs, including pasteurellosis, mastitis, metritis, enteric and urinary tract infections. Sensitive organisms include: *Streptococcus* and *Staphylococcus* spp, some *E.coli* and some *Salmonella* spp.
- In horses, especially those infections associated with *Streptococcus* spp. and *Staphylococcus* spp.

4.3 Contraindications

Do not use in case of hypersensitivity to penicillin or neomycin or to any of the excipients.
Do not administer by the intravenous route.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
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.

4.6 Adverse reactions (frequency and seriousness)

Occasionally in sucking and fattening pigs, administration of this product may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination.
In pregnant sows and gilts, a vulval discharge which could be associated with abortion has been reported.
Allergic reactions have been observed occasionally.
Local reaction (swelling) may occur at the injection site in horses for up to a week after administration.
Occasional, potentially fatal reactions associated with the administration of procaine penicillin in horses have been observed.

4.7 Use during pregnancy, lactation or lay

The product is not contra-indicated, but a vulval discharge which could be associated with abortion has been reported in pregnant sows and gilts.

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 cell 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

Dose: The dosage rate is 5 mg neomycin base per kg for cattle, pigs and horses.
Maximum dose for cattle and horses is 25 ml and for pigs is 6 ml.
The dosage interval is 24 hours
Courses of treatment should be restricted to a period of three days.

Route of administration: Deep intramuscular injection in all species, observing normal aseptic precautions.
Do not administer by the intravenous route.
Volumes greater than 15 ml should be divided over two injection sites.

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

Overdosage with neomycin parenterally can cause renal damage and deafness but this is unlikely at normal therapeutic dosage levels.
No specific treatment or antidote is recommended.

4.11 Withdrawal Period(s)

Cattle:
Meat and offal: 89 days.

Pigs:
Meat and offal: 50 days.

Horses:
Meat and offal: 6 months.

Not authorised for use in animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Penicillins, combinations with other antibacterials.
ATCvet code: QJ01RA01.

5.2 Pharmacokinetic properties

The pharmacokinetics of the product are such that the dosage interval is 24 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Lecithin
Sodium formaldehyde sulphoxylate
Mannitol
Povidone
Citric acid monohydrate
Sodium citrate buffer
Simeticone
Water for injections

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store in a refrigerator (2 ^{o}C - 8 ^{o}C). Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

10996/006/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1987

Date of last renewal: 1st October 2007

10 DATE OF REVISION OF THE TEXT

July 2015