# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphapen + Strep Procaine Penicillin 200 mg & Dihydrostreptomycin Sulphate 250 mg Suspension for Injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Active substances:**

| | |
|---|---|
| Procaine Benzylpenicillin (procaine penicillin) | 200 mg/ml |
| Dihydrostreptomycin Sulphate | 250 mg/ml |

**Excipient(s):**

| | |
|---|---|
| Nipasept sodium | 1.5 mg |
| Sodium formaldehyde sulphoxylate dihydrate | 1.25 mg |

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Suspension for injection.
A white to off-white suspension

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cattle
Horses
Sheep
Pigs

### 4.2 Indications for use, specifying the target species

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

*Corynebacterium pyogenes*
*Erysipelothrix rhusiopathiae*
*Klebsiella pneumoniae*
*Listeria* spp
*Mannheimia haemolytica*
*Pasteurella multocida*
*Staphylococcus* spp (non penicillinase producing)
*Streptococcus* spp
*Salmonella* spp
And for the control of secondary bacterial infection with sensitive organisms in diseases primarily associated with viral infection.

## 4.3 Contraindications

Contraindicated in known cases of hypersensitivity to penicillins.

## 4.4 Special warnings for each target species

Use with care in animals known to have kidney disease or defective renal function.
Do not exceed the recommended dosage or duration of treatment.

## 4.5 Special precautions for use

i. Special precautions for use in animals

Not for intravenous or intrathecal administration.
Care should be taken not to exceed the recommended dosage.
Aminoglycosides have a narrower margin of safety than beta-lactam antibiotics.
Use with care in animals known to have kidney disease or defective renal function.

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

Penicillins and Cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to Penicillins may lead to cross reactions to Cephalosporins and vice versa. Allergic reaction 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 in breathing are more serious symptoms and require urgent medical attention.

Wash hands after use

## 4.6 Adverse reactions (frequency and seriousness)

Occasionally in suckling and fattening pigs, administration may cause a transient pyrexia, vomiting, shivering, listlessness and inco-ordination. A mild transient local reaction may occur at the site of injection in horses. Additionally, in pregnant sows and gilts, a vulval discharge which could be associated with abortion has been reported.

## 4.7 Use during pregnancy, lactation or lay

Duphapen + Strep can be safely administered to pregnant and lactating animals. However, in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

## 4.8 Interaction with other medicinal products and other forms of interaction

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

## 4.9 Amounts to be administered and administration route

Shake the vial before use.
Administer by deep intramuscular injection.
Recommended dosage rate is 8mg/kg bodyweight procaine penicillin with 10 mg/kg bodyweight dihydrostreptomycin sulphate equivalent to 1 ml per 25 kg bodyweight. Treatment should be given once daily for up to three consecutive days. The maximum dose volume administered at one site should not exceed 15 ml for horses, 6ml for cattle, 3 ml for sheep and 1.5 ml for pigs.

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

No treatment specified.

## 4.11 Withdrawal periods

Animals must not be slaughtered for human consumption during treatment.

Cows: Milk: 60 hours. Milk must not be taken during treatment.
Meat: 23 days.
Sheep: Not to be used in sheep producing milk for human consumption.
Meat: 31 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.

# 5. PHARMACOLOGICAL PROPERTIES

**Pharmacotherapeutic group:** Antibacterials for systemic use, Combinations of antibacterials.

**ATC Vet Code:** QJ01RA01

Penicillin G is a beta-lactam antibiotic and its structure contains the beta-lactam ring and thiazolidine ring common to all penicillins. Beta-lactam antibiotics prevent the bacterial cell wall of susceptible Gram-positive bacteria from

forming by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes which catalyse cross-linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action but cause lysis only of growing cells.

Dihydrostreptomycin is an aminoglycoside antibiotic active against gram-negative aerobes, which after penetration of the cell envelope binds to receptors on the 30S sub unit of the bacterial ribosome. It induces misreading of the genetic code on the ribonucleic acid (mRNA) template, causing bacteriostasis. Aminoglycosides exert synergistic action in combination with beta-lactam antibiotics.

After injection of Duphapen + Strep, the procaine penicillin is rapidly absorbed from the site of injection, with maximum penicillin levels of between 1 and 2µg/ml for horses, sheep and pigs and 0.5µg/ml for cattle, being obtained with two hours of injection.

The penicillin elimination half-lives are approximately two hours for sheep and pigs, five hours for cattle and 11 hours for horses.

Dihydrostreptomycin is absorbed at a similar rate, with maximum plasma levels of 23µg/ml being obtained for cattle, sheep and pigs and 15µg/ml for hoses. The elimination half-lives are approximately two hours for cattle, sheep and pigs and four hours for horses.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Nipasept sodium
Povidone K12
Polysorbate 80
Sodium citrate dihydrate
Procaine Hydrochloride
Sodium formaldehyde sulphoxylate dihydrate
Cetrimide
Hydroxybenzoate esters
Citric acid anhydrous
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°C to +8°C).
Protect from light.

## 6.5 Nature and composition of immediate packaging

Clear type II multidose glass vials of 50 ml and 100 ml containing a white to off-white sterile aqueous suspension.
Not all pack sizes may be marketed.

## 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

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

## 8. MARKETING AUTHORISATION NUMBER

**Vm** 42058/4045

## 9. DATE OF FIRST AUTHORISATION

**Date:** 07 April 1992

## 10. DATE OF REVISION OF THE TEXT

**Date:** April 2014

03 April 2014