PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains Procaine Benzylpenicillin (Procaine Penicillin) 200 mg, Dihydrostreptomycin Sulphate 250 mg, Nipasept sodium 1.5 mg (antimicrobial preservative) and sodium formaldehyde sulphoxylate dihydrate 1.25 mg (antioxidant).

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, cattle, sheep and 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

SHAKE THE VIAL WELL BEFORE USE.

For intramuscular injection. Recommended dose rate 1 ml per 25 kg bodyweight for up to three consecutive days.

8. WITHDRAWAL PERIOD

Cows: Milk: 60 hours. Milk must not be taken during treatment.

Meat: 23 days

Sheep: Not to be used in sheep producing milk intended 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.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillin/Cephalosporin may occasionally cause severe allergic reactions. See package leaflet for operator warning.

Occasionally in suckling and fattening pigs, administration of this product may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination. 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.

Care should be taken not to overdose.

Contra-indicated in known cases of hypersensitivity to penicillins

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (+2°C to +8°C). Protect from light.

Following withdrawal of the first dose, use the product within 28 days. Once broached use by …

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]*

POM-V

For animal treatment only. 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

Zoetis UK Limited

5th Floor, 6 St. Andrew Street

London, EC4A 3AE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4045

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR: Duphapen + Strep Procaine Penicillin 200 mg & Dihydrostreptomycin Sulphate 250 mg Suspension for Injection

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

Zoetis UK Limited

5th Floor, 6 St. Andrew Street

London, EC4A 3AE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

A sterile white aqueous suspension for injection.

Each ml contains:

Procaine Benzylpenicillin (Procaine penicillin) 200 mg

Dihydrostreptomycin Sulphate 250 mg

The product also contains nipasept sodium 1.5 mg as antimicrobial preservative and sodium formaldehyde sulphoxylate dihydrate 1.25 mg as antioxidant.

4. INDICATION(S)

Duphapen + Strep is indicated for use in cattle, horses, sheep and pigs for the treatment of infections 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, *Streptococcus* spp, and *Salmonella* spp.

Duphapen + 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

Do not use in known cases of hypersensitivity to penicillin.

Not suitable for intravenous or intrathecal administration.

6. ADVERSE REACTIONS

Occasionally in suckling and fattening pigs, administration of this product may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination. 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.

7. TARGET SPECIES

Horses, cattle, sheep and pigs

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

Shake the vial well before use.

Duphapen + Strep should be administered by intramuscular injection. Normal aseptic precautions should be observed. The recommended dose rate for cattle, horses, pigs and sheep is 8 mg procaine penicillin and 10 mg dihydrostreptomycin sulphate per kg bodyweight achieved by administering 1 ml per 25 kg bodyweight once daily for up to 3 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

Do not administer with other antibiotics such as tetracyclines or with other aminoglycosides. Aminoglycosides have a narrower margin of safety than beta-lactam antibiotics.

10. WITHDRAWAL PERIOD(S)

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.

11. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (+2°C to +8°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.

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 container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Use with care in animals known to have kidney disease or defective renal function.

Do not exceed the recommended dosage or duration of treatment.

For animal treatment only

OPERATOR WARNINGS

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 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

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

May 2013

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.

PACKAGE QUANTITIES

Multidose vials of 50 ml and 100 ml. Not all pack sizes may be marketed.

Vm 42058/4045

Approved: 18/01/2018