

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphaphen 300 mg/ml Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A white to off-white suspension for injection containing Procaine Penicillin 300 mg/ml. Also contains mixed hydroxybenzoate esters (as sodium salts) 1.5 mg/ml as preservative.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, sheep and pigs

6. INDICATION(S)

Duphaphen Injection is indicated for use in cattle, sheep and pigs in the treatment of systemic infections caused by or associated with organisms sensitive to penicillin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer by the intramuscular route after shaking to ensure resuspension. Normal aseptic precautions should be observed. The recommended dose rate is 10 mg/kg bodyweight (1 ml/30 kg) daily for three to five days.

8. WITHDRAWAL PERIOD

Cattle: Meat: 7 days. Milk: 84 hours.

Pigs: Meat: 7 days.

Sheep: Meat: 7 days.

Do not use in sheep producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use. **User warnings**

Penicillins/cephalosporins may occasionally cause severe allergic reactions: see package leaflet for user warning.

Wash hands after use

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Keep container in the outer carton.

Do not store above 25°C. Protect from light.

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

Discard unused material.

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 reach and sight 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 42058/4046

17. MANUFACTURER’S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphaphen 300 mg/ml Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: 300 mg Procaine Penicillin in an aqueous suspension and mixed hydroxybenzoate esters (as sodium salts) 1.5 mg as antimicrobial preservative. For the treatment of infections caused by, or associated with organisms sensitive to penicillin.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, sheep and pigs

6. INDICATION(S)

For the treatment of systemic infections caused by or associated with organisms sensitive to penicillin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

SHAKE VIAL BEFORE USE (TO ENSURE RESUSPENSION).

For intramuscular injection. Recommended dose rate is 10 mg Procaine Penicillin per kg bodyweight (1 ml per 30 kg) for 3-5 days.

8. WITHDRAWAL PERIOD

Cattle: Meat: 7 days. Milk: 84 hours.

Pigs: Meat: 7 days.

Sheep: Meat: 7 days.

Do not use in sheep producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Occasionally, in suckling and fattening pigs, administration of such products 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. Do not inject intravenously. Care should be taken not to overdose. Duphaphen is contraindicated in known cases of hypersensitivity to penicillins.

User warnings

Penicillins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Keep container in the outer carton.

Do not store above 25°C. Protect from light.

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

Discard unused material.

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

Further information: Read the package leaflet before use.

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 reach and sight 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 42058/4046

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR: Duphapen 300 mg/ml 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 300 mg/ml Suspension for Injection

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

PRESENTATION

A white to off-white suspension for injection containing Procaine Penicillin 300 mg/ml. Also contains mixed hydroxybenzoate esters (as sodium salts) 1.5 mg/ml as preservative.

4. INDICATION(S)

Duphapen Injection is indicated for use in cattle, sheep and pigs in the treatment of systemic infections caused by or associated with organisms sensitive to penicillin. *In vitro* tests have shown the following organisms to be sensitive: *Arcanobacterium pyogenes*, *Erysipelothrix rhusiopathiae*, *Listeria*, *Mannheimia haemolytica*, *Pasteurella multocida*, *Staphylococcus* spp. (non-penicillinase producing) and *Streptococcus* spp.

Duphapen is recommended, therefore, in the treatment of diseases caused by susceptible organisms including: erysipelas; navel/joint-ill; respiratory tract infections including pneumonia and atrophic rhinitis; listeriosis; septicaemia; urogenital tract infections and the control of secondary bacterial invaders in diseases of primary viral origin.

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to penicillins.

Do not inject intravenously or intrathecally.

Not to be used in small herbivores such as guinea pigs, gerbils and hamsters.

Care should be taken not to overdose.

6. ADVERSE REACTIONS

Occasionally in suckling and fattening pigs administration of products containing procaine penicillin 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.

7. TARGET SPECIES

Cattle, sheep and pigs

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

Duphaphen should be administered by the intramuscular route after shaking to ensure resuspension. Normal aseptic precautions should be observed. The recommended dose rate is 10 mg/kg bodyweight (1 ml/30 kg) daily for three to five days.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information.

10. WITHDRAWAL PERIOD(S)

Cattle: Meat: 7 days.

Milk: 84 hours.

Pigs: Meat: 7 days.

Sheep: Meat: 7 days.

Do not use in sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light.

Keep out of the reach and sight of children. Following withdrawal of the first dose, use the product within 28 days. Discard any unused material. Do not use after the stated expiry date on the carton and label.

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.

Keep container in the 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 penicillin may lead to cross-reactions to cephalosporins and vice-versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations. Handle this type of product with great care to avoid exposure taking all recommended precautions.

If you develop symptoms following exposure such as 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.

For animal treatment only

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 40 ml and 100 ml. Not all pack sizes may be marketed.

Vm 42058/4046

Reviewed: January 2018
(Amended pages)

Approved: 18/01/2018

A handwritten signature in black ink, appearing to read 'J. King', positioned below the approval date.