SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphapen 300 mg/ml Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Procaine Penicillin 300 mg/ml

Excipient(s):
Methyl parahydroxybenzoate 1.1 mg/ml
Ethyl parahydroxybenzoate 0.23 mg/ml
Propyl parahydroxybenzoate 0.16 mg/ml

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, Sheep & Pigs

4.2 Indications for use, specifying the target species

For 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)
Streptococcus spp.

Duphapen is recommended therefore to be effective 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.

4.3 Contraindications

Do not inject intravenously or intrathecally.
Do not use in known cases of hypersensitivity to penicillin.
Not to be used on very small herbivores such as guinea pigs, gerbils and hamsters.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) Special precautions for use in animals

Shake the container before use.
Care should be taken not to overdose.
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.

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

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 penicillins 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 product with great care to avoid exposure, taking all recommended precautions.

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)

Occasionally in sucking and fattening pigs, administration may cause a transient pyrexia, vomiting, shivering, listlessness and inco-ordination.

4.7 Use during pregnancy, lactation or lay

Duphapen 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

None known.

4.9 Amounts to be administered and administration route

Administer by deep intramuscular injection only.
The recommended dose rate is 10 mg/kg bodyweight (1 ml/30 kg) daily for 3 to 5 days.
To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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

Penicillins have a wide margin of safety.

4.11 Withdrawal periods

Cattle: Meat – 7 days
Milk – 84 hours

Sheep: Meat – 7 days
Milk – Not for use in sheep producing milk for human consumption.

Pigs: Meat – 7 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use
ATC Vet Code: QJ01CE09

5.1 Pharmacodynamic properties

Antimicrobial activity is achieved by interference in the final stage of bacterial cell wall synthesis by binding to the PBP's (penicillin binding proteins).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Ethyl parahydroxybenzoate
Propyl parahydroxybenzoate
Povidone K12
Disodium edetate dihydrate
Potassium dihydrogen phosphate
Sodium citrate dihydrate
Polysorbate 80
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

Do not store above 25^{o}C.
Protect from light.

6.5 Nature and composition of immediate packaging

Sterile, white aqueous injection in clear Type II multidose glass vials of 40 ml and 100ml closed with nitryl rubber bungs with aluminium caps.
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 42058/4046

9. DATE OF FIRST AUTHORISATION

Date: 22 December 1971

10. DATE OF REVISION OF THE TEXT

Date: April 2014

03 April 2014