

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphaphen 300 mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:

Procaine Benzylpenicillin 300 mg

Excipients:

Hydroxybenzoate ester (as preservative) 1.5 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

Horses, Cows, 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:

Corynebacterium pyogenes

Erysipelothrix rhusiopathiae,

Listeria spp.

Pasteurella haemolytica

Pasteurella multocida,

Staphylococcus spp (non-penicillinase producing)

Streptococcus spp.

4.3 Contraindications

Do not inject intravenously.

Do not use in known cases of hypersensitivity to penicillins.

Not for use in sheep producing milk for human consumption.

4.4 Special warnings for each target species

Occasionally in suckling and fattening pigs administration of Duphaphen may cause a transient pyrexia, vomiting, shivering, listlessness and in-coordination.

4.5 Special precautions for use

Special precautions for use in animals

Administer by deep intramuscular injection only.

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 reaction to these substances are occasionally 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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Occasional, potentially fatal reactions associated with the administration of procaine penicillin in horses have been observed.

4.7 Use during pregnancy, lactation or lay

Duphaphen 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 intramuscular route after shaking to ensure re-suspension. Normal aseptic precautions should be observed. The recommended dosage rate is 10 mg Procaine Penicillin/kg bodyweight equivalent to 1 ml per 30 kg bodyweight daily for 3 -5 days.

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

Not applicable.

4.11 Withdrawal Period(s)

Milk for human consumption must not be taken during treatment.

Milk for human consumption may only be taken from cows after 72 hours after the last treatment.

Animals must not be slaughtered for human consumption during treatment.

Cattle, sheep and pigs may be slaughtered only after 5 days from last treatment.

Horses intended for human consumption must not be slaughtered until 28 days after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use, Procaine penicillin.

ATCvet Code: QJ01CE09.

5.1 Pharmacodynamic properties

Procaine Penicillin is administered by deep intramuscular injection to create a depot from which benzylpenicillin is slowly liberated. It exerts its effect on multiplying bacteria by interfering with the formation of the cell wall.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone

Disodium edetate

Potassium dihydrogen orthophosphate

Sodium citrate

Polysorbate 80

Hydroxybenzoate ester (Nipasept (as sodium salt))

Lecithin

Antifoam M30

Potassium chloride

Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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°C.

Protect from light.

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is presented in clear colourless Type II (Ph. Eur.) 100 ml multidose glass vials sealed with nitril rubber bungs and aluminium seals.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/038/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 September 2007

10 DATE OF REVISION OF THE TEXT

April 2012
August 2013