Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dipen 100ml Suspension for Injection for cattle, sheep and pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Procaine benzylpenicillin	200	mg
Dihydrostreptomycin (as dihydrostreptomycin sulphate)	200	mg

Excipients

Methyl parahydroxybenzoate	1.0	mg
Sodium formaldehyde sulfoxylate	0.423	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for Injection
The product is a white to off-white sterile aqueous suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

For the treatment of infections caused by bacteria sensitive to penicillin and dihydrostreptomycin in cattle, sheep and pigs.

4.3 Contraindications

Do not administer to animals known to be sensitive to penicillin. Do not use when it is known that penicillinase-producing staphylococcus organisms are present.

4.4 Special warnings for each target species

Occasionally in sucking and fattening pigs, administration of products containing procaine penicillin may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination.

In pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.
The maximum dose volume recommended at any one site for cattle is 20 ml.

4.5 Special precautions for use

Special precautions for use in animals

Use of this 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 (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Whenever possible the product should only be used on the basis of susceptibility testing.

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 those substances can 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.

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 allergies to penicillins have been observed but these are very rare. Hypersensitivity (allergic) reactions to penicillins can vary from localised swelling to anaphylaxis and death.
Occasionally in sucking and fattening pigs administration of products containing procaine penicillin may cause transient pyrexia, vomiting, shivering, listlessness and incoordination.
In pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported. Procaine penicillin G can, under certain circumstances, be toxic and even lethal to pigs and this is thought to be due to a sudden release of toxic amounts of free procaine. The symptoms include shivering, lassitude, inappetence, vomiting, cyanosis of the extremities and pronounced pyrexia (40°C and over). A vulval discharge may appear and some animals may abort. Alarming side-effects are most likely to occur when pigs with erysipelas are injected with an older and, or, heat-affected procaine penicillin formulation. Treatment with 5 mg dexamethasone will result in rapid recovery.

4.7 Use during pregnancy, lactation or lay

Pregnancy
Procaine penicillin and dihydrostreptomycin are safe for use in pregnant animals.

Lactation
Not for use in lactating ewes producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interactions

Tetracyclines are bacteriostatic antibiotics that presumably may interfere with a bactericidal agent such as penicillin. Since penicillin acts by inhibiting cell wall synthesis, agents such as tetracyclines, which inhibit protein synthesis, could mask the bactericidal effect of penicillin.

If penicillin is used with a tetracycline, it would be prudent to observe the following points when possible:

1. Be sure that adequate amounts of each agent are given; antagonism is most likely to occur when barely sufficient amounts of each agent are given.

2. Begin administration of the penicillin at least a few hours before the administration of tetracycline.

4.9 Amounts to be administered and administration route

The recommended dose is 4 ml per 100 kg bodyweight i.e. 8 mg procaine penicillin and 10 mg dihydrostreptomycin sulphate per kg. The dose should be given once daily for up to 3 consecutive days.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid under-dosing.
For intramuscular administration only.

Species	Dose (ml)	kg Bodyweight
Cattle	4.0	100
Calf	2.0	50
Sheep	1.0	25
Lamb	0.4	10
Sow	3.0	75
Piglet	0.2	5

Clean the area of injection and swab with spirit.
The maximum dose volume recommended at any one site for cattle is 20 ml.
Administer alternately on the left side and the right side.

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

Do not exceed the stated dose.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 21 days.
Milk: 72 hours.

Sheep:
Meat and offal: 21 days
Milk: Not to be used in lactating ewes producing milk for human consumption.

Pigs:
Meat and offal: 21 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Penicillins, combinations with other antibacterials.
ATCvet Code: QJ01RA01

5.2 Pharmacokinetic particulars

Penicillins are rapidly absorbed when injected in an aqueous suspension by the intramuscular route. However, absorption of Penicillin G from procaine penicillin preparation is prolonged, with peak blood levels being attained at approximately 2-4 hours and declining below therapeutic levels at 24 hours in pigs and 48 hours in cattle and sheep.

Dihydrostreptomycin is also absorbed rapidly. Peak plasma concentration occurs within 1 hour. The blood levels will decline a lot faster (below therapeutic levels at 12 hours) than the penicillin G due to a slower absorption of the penicillin from the procaine preparation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate
Sodium Formaldehyde Sulfoxylate
Povidone K12
Sodium Citrate
Potassium dihydrogen phosphate
Simethicone emulsion
Disodium Edetate
Water for Injection

6.2 Major 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 immediate packaging: 4 weeks

6.4 Special precautions for storage

Store in a refrigerator ($^{+}2^{o}$C to $^{+}8^{o}$C)
Do not freeze.

6.5 Nature and composition of immediate packaging

Type II, siliconised clear glass, 100 ml vials containing an aqueous, sterile suspension, closed with nitryl rubber stoppers and sealed with aluminium seals.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 March 2006
Date of last renewal: 02 March 2011

10 DATE OF REVISION OF THE TEXT

May 2019