SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depocillin 300 mg/ml suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance per ml:
Procaine benzylpenicillin 300 mg

Preservative:
Methylparahydroxybenzoate 1.10 mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cow, horse, sheep, pig, dog and cat

4.2 Indications for use, specifying the target species

Depocillin is indicated for the treatment of infections caused by bacteria sensitive to penicillin.

4.3 Contra-indications

Not to be administered to animals sensitive to penicillin.
Not to be used in rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in any other small herbivores.
Not effective against beta-lactamase producing organisms.

4.4 Special warning 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. Additionally in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

4.5 Special precautions for use.

i. Special precautions for use in animals

Not recommended for intravenous or intrathecal administration

ii. Special precautions to be taken by the person administering the 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 reactions to cephalosporins and *vice versa*. Allergic reactions 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 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)

Hypersensitivity reactions may occur in very rare cases. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening. Potentially fatal reactions associated with the administration of procaine penicillin in horses have been observed. If such reactions occur appropriate treatment is recommended.
In sucking and fattening pigs, vomiting has been observed in very rare cases. Injection site reactions such as swelling and pain have been recorded with post-marketing data in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

No special precautions necessary

4.8 Interaction with other medicinal products and other forms of interaction

Antagonism between the product and bacteriostatic preparations may occur. Resistant bacteria, particularly gram-negative, that show a cross-resistance with other ß-lactam antibiotics might occur.

4.9 Amounts to be administered and administration route

Horses and cattle 12 mg/kg bodyweight, sheep and pigs 15 mg/kg by intramuscular injection.
Dogs and cats 30 mg/kg (1ml per 10 kg body weight) by subcutaneous administration.

Suggested doses are:

Horse	500	kg	20	ml
Cow	500	kg	20	ml
Sheep	50	kg	2.5	ml
Pig	50	kg	2.5	ml
Dog	10	kg	1	ml
Cat	5	kg	0.5	ml

Clean the area of the injection site and swab with spirit. Shake well before use.
Treatment may be repeated at 24 hour intervals for up to 5 administrations. For organisms highly susceptible to penicillin, such as *Streptococcus dysgalactiae* in sheep, treatment may be repeated at 48 hour intervals for up to 3 administrations.

DO NOT USE THE SAME INJECTION SITE MORE THAN ONCE DURING A COURSE OF TREATMENT.
Do not inject more than 20 ml per injection site in cattle.
Do not inject more than 5 ml per injection site in pigs and sheep.

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

Penicillin is a compound with a very high therapeutic ratio. It is very unlikely that an overdose of the product will have adverse effects on the treated animal.

4.11 Withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero

Meat:	Cattle	5 days
	Pigs	5 days
	Sheep	5 days
Milk:	(Cows only)	264 hours (11 days)

Not to be used in sheep producing milk intended for human consumption.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: QJ01CE09

Pharmacotherapeutic group: Antibacterials for systemic use, Beta-lactam

antibacterials, penicillins, Beta-lactamase sensitive penicillins

Pharmacokinetic particulars

Penicillin is a beta-lactam antibiotic which has bactericidal activity against mainly Gram-positive bacteria and some Gram-negative aerobes. It is sensitive to beta-lactamase (penicillinase) inactivation. It is widely distributedin the extracellular fluids after absorption, and eliminated almost entirely by the kidneys.
The procaine penicillin gives high initial blood levels; treatment may be repeated at 24 or 48 hour intervals to maintain therapeutic levels.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate
Lecithin (soya)
Povidone (K30)
Sodium Citrate dihydrate
Potassium Acid Phosphate
Disodium Edetate Dihydrate
Sodium hydroxide 32% (for pH adjustment)
Phosphoric acid 85% (for pH adjustment)
Water for injections

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life: 3 years
Following withdrawal of the first dose, use the product within 28 days.

6.4 Special precautions for storage

Store in a refrigerator at between +2^{o}C and +8^{o}C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Multidose vials of neutral (Ph.Eur. type II) glass or PET closed with halogenated butyl rubber stoppers and aluminium closures, containing 100 ml.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4081

9. DATE OF FIRST AUTHORISATION

25 September 1996

10. DATE OF REVISION OF TEXT

June 2024

Approved 28 June 2024
Gavin Hall