

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Crystapen 5 Mega 95.7% w/w Powder for Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains

Active substance

Benzylopenicillin	3g*
(as Benzylopenicillin Sodium Ph. Eur.	95.7 % w/w)
*equivalent to 5 mega-units of benzylopenicillin	

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

A white powder for solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

For the treatment and control of systemic infections caused by or associated with organisms sensitive to penicillin including:

Gram-positive bacteria

Arcanobacterium pyogenes
Erysipelothrix rhusiopathiae
Listeria spp.
Rhodococcus equi
Staphylococcus aureus
Streptococcus zooepidemicus

Gram-negative bacteria

Klebsiella pneumoniae
Mannheimia haemolytica
Pasteurella multocida
Proteus spp.
Pseudomonas aeruginosa
Some *Salmonella* spp.

4.3 Contraindications

Do not use in known cases of hypersensitivity to penicillins.

4.4 Special warnings for each target species

No special warnings are considered necessary.

4.5 Special precautions for use

Special precautions for use in animals

The usual aseptic precautions should be followed when administering the product.

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

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Skin sensitisation may occur in persons handling penicillin and occasionally this sensitivity may be of a severe degree. It is therefore important that appropriate protective measures should be taken to avoid contact with preparation.

Do not handle the 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 the 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

The product may be used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The recommended dosage is 10 mg/kg bodyweight twice daily for 1 day by intravenous injection. Each vial contains 3 g benzylpenicillin. To ensure a correct dosage bodyweight should be determined as accurately as possible to avoid underdosing. The usual aseptic precautions should be followed. The following guide is given to enable practical dose volumes to be administered.

Animal Weight (kg)	Reconstitution water volume (ml) per vial	Volume of reconstituted material for administration (ml)	Dosage (mg/kg)
50	18.0	3.0	10.0
75	10.0	2.5	10.0
100	10.0	3.3	10.0
150	10.0	5.0	10.0
200	6.0	4.0	10.0
500	6.0	10.0	10.0

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

There are no specific recommendations in the case of overdosage

4.11 Withdrawal Period(s)

Do not slaughter animals for human consumption until 28 days after treatment. Meat and offal: 28 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactam antibacterials.

ATCvet Code: QJ01CE01

5.1 Pharmacodynamic properties

Benzylpenicillin is a narrow spectrum antibiotic which has a bacteriostatic effect at low concentrations (minimum of 0.03 units per ml) and is bactericidal at higher concentrations to organisms in the growth phase (0.5 units per ml). Penicillin is active primarily against gram-positive bacteria. Its action is unaffected by blood or pus and it does not affect leucocyte metabolism.

Benzylpenicillin acts by inhibiting the biosynthesis of cell wall mucopeptide without interfering in protein synthesis. When cell growth takes place in the absence of a properly constituted cell wall, death of the cell occurs by lysis.

5.2 Pharmacokinetic properties

Following intravenous injection in the horse, peak levels of around 30 micrograms/ml are measured in the plasma. These decline to undetectable levels by 12 hours after injection. The plasma half life of benzylpenicillin in the horse is around 75 minutes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trisodium Citrate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after reconstitution according to directions: 24 hours

6.4 Special precautions for storage

Do not store above 25°C.

Reconstituted solutions may be stored for a maximum of 24 hours at 2°C - 8°C.

6.5 Nature and composition of immediate packaging

30ml Type I or III glass vial sealed with a butyl rubber stopper containing a sterile soluble dry powder for reconstitution with water for injections BP/Ph. Eur.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Limited,
Shire Park,
Welwyn Garden City,
Hertfordshire,
AL7 1TW,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/024/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT

29th November 2010