SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product

Crystapen 5 Mega Units 3g
Powder for solution for injection

2. Qualitative and Quantitative Composition

Active ingredients	**per vial**
Benzylpenicillin	3.00g*
(as Benzylpenicillin Sodium	95.7 % w/w)

*equivalent to 5 mega-units of benzylpenicillin

Excipients
For a full list of excipients see section 6.1

3. Pharmaceutical Form

Powder for solution for Injection.
White crystalline powder.

4. Clinical Particulars

4.1 Target Species

Horses.

4.2 Indications for Use

For the treatment and control of acute and severe systemic infections caused by or associated with organisms sensitive to penicillin including: *Arcanobacterium pyogenes, Erysipelothrix rhusiopathiae, Klebsiella pneumoniae, Listeria* spp*, Mannheimia haemolytica, P multocida, Proteus* spp*, Pseudomonas aeruginosa, Rhodococcus equi, Staphylococcus aureus, Streptococcus zooepidemicus,* some *Salmonella* spp.

4.3 Contra-indications

Do not use in known cases of hypersensitivity to penicillins. Do not use in small mammals (eg. gerbils, rabbits).

4.4 Special Warnings for each Target Species

Penicillins 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 use in animals known to be sensitive to penicillin.

4.5 Special precautions for Use

(i) Special precautions for use in animals

The usual aseptic precautions should be followed when administered the product. Not for intrathecal administration.
Use of the product should be based on susceptibility testing of 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.

(ii) Special precautions to be taken by the person administering the 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 sensitive to penicillins, 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 thoroughly after use.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions in susceptible animals, diarrhoea.

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 10mg/kg bodyweight twice daily for 1 day by intravenous injection. 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
Note : Each vial contains 3g of benzylpenicillin			

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

4.10 Overdose (symptoms, emergency procedures, antidotes)

The product is well tolerated at twice the dose.

4.11 Withdrawal Period

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

ATC Vet code QJ01CE01
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.

5.1 Pharmacodynamic properties

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

Sodium citrate anhydrous

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 at 2-8ºC.

6.4 Special Precautions for Storage

Do not store above 25ºC.
Reconstituted solutions may be stored for maximum of 24 hours at 2-8ºC.

6.5 Nature and Composition of immediate packaging

30 ml colourless glass type III vial with grey rubber bromobutyl bung with aluminium overseal.

6.6 Special Precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such product, if any

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

7. MARKETING AUTHORISATION HOLDER

Intervet UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4597

9. DATE OF FIRST AUTHORISATION

Date: 05 December 1990

10. DATE OF REVISION OF THE TEXT

Date: January 2014.

10 January 2014