PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {BOX LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Crystapen™ 5 Mega Units 3g

Powder for Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each vial contains Benzylpenicillin Sodium 95.7% w/w (equivalent to 3g or 5 mega-units of Benzylpenicillin).

3. PHARMACEUTICAL FORM

Powder for Solution for Injection

4. PACKAGE SIZE

25x3g vials

5. TARGET SPECIES

For use in horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Not to be used in horses intended for human consumption.

Read package leaflet before use for full warnings and disposal advice.

Penicillins and cephalosporins may cause severe allergic reactions, see package leaflet for full user warnings.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

Reconstituted solution may be stored for 24 hours at 2-8ºC.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet before use for full warnings and disposal advice.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

FOR ANIMALTREATMENT ONLY.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder

Intervet UK Ltd.

Walton, Milton Keynes MK7 7AJ

Distributor in N. Ireland:

Intervet Ireland Ltd. Dublin 24,

Ireland**.**

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4597

17. MANUFACTURER'S BATCH NUMBER

Expiry End of:

Lot No.:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Crystapen™ 5 Mega Units 3g

Powder for Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each vial contains Benzylpenicillin Sodium 95.7% w/w (equivalent to 3g or 5 mega-units of Benzylpenicillin).

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

IV injection in horses

Read package leaflet before use.

Not to be used in horses for human consumption.

Do not store above 25ºC.

Once reconstituted use within 24 hours at 2 – 8ºC.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch no:

7. EXPIRY DATE

EXP end of:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

KEEP OUT OF SIGHT AND REACH OF CHILDREN

POM-V

To be supplied only on veterinary prescription.

Vm 01708/4597

MA holder

Intervet UK Ltd. Walton, Milton Keynes MK7 7AJ

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

Manufacturer for batch release:

Sandoz GmbH Biochemiestrasse 10 A-6250 Kundle, Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Crystapen™ 5 Mega Units 3g

Powder for Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Per vial: Benzylpenicillin 3.00g* (as Benzylpenicillin Sodium 95.7% w/w)

*equivalent to 5 mega-units of Benzylpenicillin

4. INDICATION(S)

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 haemofytica, P multocida, Proteus spp, Pseudomonas aeruginosa, Rhodococcus equi, Staphylococcus aureus, Streptococcus zooepidemicus*, some Salmonella spp.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Hypersensitivity reactions in susceptible animals, diarrhoea.

7. TARGET SPECIES

Horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended dosage is 10mg/kg bodyweight twice daily for 1 day by intravenous injection.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

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.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Reconstituted solutions may be stored for maximum of 24 hours at 2-8°C. Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

The usual aseptic precautions should be followed when administering 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.

USER WARNINGS

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2013

15. OTHER INFORMATION

For animal treatment only.

Pack size: 3 g vial.

POM-V To be supplied only on veterinary prescription.

Vm 01708/4597

Licensed distributor in N. Ireland: Intervet Ireland Ltd. Magna Drive, Magna Business Park City West Road, Dublin 24 , Ireland.

Approved: 08/06/2017