PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEPOCILLIN 300 mg/ml Suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

PROCAINE BENZYLPENICILLIN
Preservative methylparahydroxy benzoate 1.1 mg/ml.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, cattle, sheep, pigs, dogs and cats.

6. INDICATION(S)

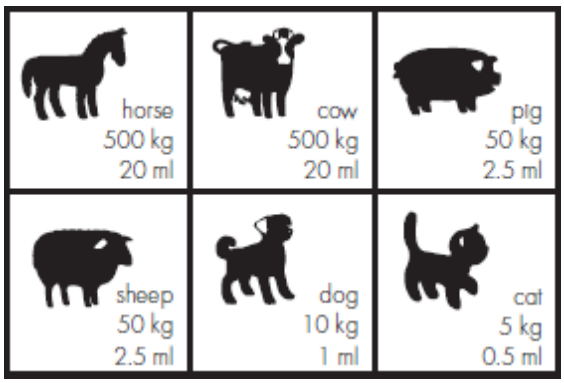
Aqueous suspension for injection for the treatment of horses, cattle, sheep, pigs, dogs and cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To be used in accordance with the directions of a veterinary surgeon.
SHAKE WELL BEFORE USE
Avoid the introduction of contamination during use.
I.M. + S.C.
Read package leaflet for further information, disposal advice and warnings before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:
Milk: (Cows only) 11 days (264 h)
Meat: Cattle - 5 days
Pigs - 5 days
Sheep - 5 days
Not for use in horses intended for human consumption.
Not for intravenous administration.



9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for further information, disposal advice and warnings before use.
Penicillins/cephalosporins may occasionally cause severe allergic reactions. See insert for user warnings.

10. EXPIRY DATE

EXP end of:
Following removal of the first dose use within 28 days.
Discard unused contents.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator at between +2°C and +8°C.
Do not freeze.
Protect from light.
Keep vial in this carton.

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

Read package leaflet for further information, disposal advice and warnings before use.

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

FOR ANIMAL TREATMENT ONLY
To be supplied only on veterinary prescription.

POM-V

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Distributed in Northern Ireland by:
INTERVET IRELAND Ltd.
Magna Drive, Magna Business Park
Citywest Road, DUBLIN 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4622
UK authorised veterinary medicinal product.

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEPOCILLIN 300 mg/ml Suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

PROCAINE BENZYLPENICILLIN

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

For the treatment of horses, cattle, sheep, pigs, dogs and cats.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M. + S.C.
SHAKE WELL BEFORE USE
Read package leaflet for further information and warnings before use
Avoid the introduction of contamination during use.
To be used in accordance with the directions of a veterinary surgeon.

8. WITHDRAWAL PERIOD

Withdrawal periods:
Milk: (Cows only) 11 days
Meat: Sheep 5 days Cattle and pigs 5 days.
Not for use in horses intended for human consumption.
Not for intravenous administration.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for further information and warnings before use
Penicillins/cephalosporins may occasionally cause severe allergic reactions. See insert for user warnings.

10. EXPIRY DATE

Expiry Use
by
Following removal of the first dose use within 28 days.
Discard unused contents

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator at between +2 °C and +8 °C.
Do not freeze.
Protect from light.

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

Read package leaflet for further information and warnings before use

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distributioncategory]

FOR ANIMAL TREATMENT ONLY
To be supplied only on veterinary prescription.

POM-V

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

KEEP OUT OF REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4622

UK authorised veterinary medicinal product.

17. MANUFACTURER'S BATCH NUMBER

Batch No.

PACKAGE LEAFLET FOR:

DEPOCILLIN 300 mg/ml Suspension for injection

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

Marketing authorisation holder
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEPOCILLIN 300 mg/ml Suspension for injection

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

Presentation
A sterile, aqueous white to off-white suspension for injection containing 300 mg/ml Procaine Benzyl penicillin. Preservative methylparahydroxybenzoate 1.1 mg/ml.

4. INDICATION(S)

Uses
For the treatment of infections caused by bacteria sensitive to penicillin in horses, cattle, sheep, pigs, dogs and cats.

5. CONTRAINDICATIONS

Contra-indications, warnings, etc.

1. Not to be administered to animals sensitive to penicillin.
2. Do not use orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised when used in any other very small herbivores.
3. Not effective against beta-lactamase producing organisms.
4. 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.

Not recommended for intravenous or intrathecal administration

6. ADVERSE REACTIONS

Included in “Contra-indications, warnings, etc.” section on artwork.

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).

7. TARGET SPECIES

Horses, cattle, sheep, pigs, dogs and cats.

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

Dosage and administration
Horses and cattle 12 mg per kg body weight. Sheep and pigs 15 mg per kg body weight, by intramuscular injection. Dogs and cats 30 mg per kg body weight by subcutaneous administration.

e.g.	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. Treatment may be repeatedat intervals of 24 hours for up to 5 administrations. For organisms highly susceptibleto 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.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the container well before use.
Following withdrawal of the first dose use the product within 28 days.

10. WITHDRAWAL PERIOD(S)

Included in “Contra-indications, warnings, etc.” section on artwork:
Withdrawal periods:
Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken only from cows only after 11 days (264 h) from the last treatment. Not to be used in sheep producing milk intended for human consumption.
Animals must not be slaughtered for human consumption during treatment. Cattle and pigs may be slaughtered for human consumption only after 5 days from the last treatment.
Sheep may be slaughtered for human consumption only after 5 days from the last treatment.
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

Pharmaceutical precautions
Store in a refrigerator at between +2°C and +8°C.
Do not freeze.
Protect from light.

12. SPECIAL WARNING(S)

Included in “Contra-indications, warnings, etc.” section on artwork:
Operator warnings:
Penicillins 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.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2021

15. OTHER INFORMATION

FOR ANIMAL TREATMENT ONLY.
KEEP OUT OF REACH AND SIGHT OF CHILDREN.
Legal category
To be supplied only on veterinary prescription

POM-V

Package quantities Multidose vials of 100 ml
Further information
Nil
Marketing authorisation number
Vm 01708/4622
MA Holder:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Distributed in Northern Ireland by:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park,
Citywest Road,
Dublin 24, Ireland

Approved: 15/10/21