LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCLAV INJECTION FOR CATTLE AND DOGS

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

This product contains amoxicillin 140 mg/ml as amoxicillin trihydrate and clavulanic acid 35mg/ml as potassium clavulanate in an oily base.

3. PHARMACEUTICAL FORM

Suspension for Injection.

4. PACKAGE SIZE

50 ml /100 ml multidose vial.

5. TARGET SPECIES

Cattle and Dogs.

6. INDICATION(S)

Noroclav Injection has a notably broad spectrum of bactericidal activity against the bacteria commonly found in cattle and dogs.

(a) *In vitro* Noroclav Injection is active against a wide range of clinically important bacteria including:
Gram-positive: Staphylococci (including beta-lactamase producing strains), Streptococci, Corynebacteria, Clostridia, *Bacillus anthracis*, *Actinomyces bovis*.
Gram-negative: *Escherichia coli* (including beta-lactamase producing strains), *Salmonella* spp, (including beta-lactamase producing strains), *Campylobacter* spp, *Klebsiella* spp, *Proteus* spp, *Pasteurellae* spp, *Fusobacterium necrophorum*, *Bacteroides* spp (including beta-lactamase producing strains), *Haemophilus* spp, *Moraxella* spp and *Actinobacillus lignieresi.*

(b) Noroclav Injection is indicated for the treatment of diseases including:

In cattle these include:
Respiratory infections
Soft tissue infections (e.g. joint/navel ill, abscesses etc.)
Metritis
Mastitis
In dogs these include:
Respiratory tract infections
Urinary tract infections
Skin and soft tissue infections (e.g. abscesses, pyoderma, anal sacculitis and gingivitis)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: By intramuscular injection at a dosage rate of 8.75 mg/kg bodyweight (equivalent to 1 ml per 20 kg bodyweight) daily for 3 to 5 days.

Dogs: By subcutaneous injection at a dosage rate of 8.75 mg/kg bodyweight (equivalent to 1 ml per 20 kg bodyweight) daily for 3 to 5 days.

Shake the vial well before use. Use a completely dry needle and syringe. Swab the septum before removing each dose. After injection massage the injection site.

8. WITHDRAWAL PERIOD

Cattle must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 42 days from the last treatment.

Milk for human consumption should not be taken during treatment. Milk for human consumption may be taken from treated cattle only after 80 hours from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

The product should not be administered to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in other very small herbivores. Do not use in animals with known hypersensitivity to penicillin or other substances of the beta-lactam group. **Penicillins and cephalosporins may occasionally cause severe allergic reactions. See packaging text for user warnings.**

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Once a vial has been broached the contents should be used within 28 days.

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

UK Only

POM-V

To be supplied only on veterinary prescription.

Vm: 02000/4185

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

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)

Norbrook Laboratories Limited,
Station Works
Camlough Road,
Newry,
County Down,
Northern Ireland
BT35 6JP

16. MARKETING AUTHORISATION NUMBER(S)

VM 02000/4185

17. MANUFACTURER'S BATCH NUMBER

Once broached use by :

CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOROCLAV INJECTION FOR CATTLE AND DOGS

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

This product contains amoxicillin 140 mg/ml as amoxicillin trihydrate and clavulanic acid 35 mg/ml as potassium clavulanate.

3. PHARMACEUTICAL FORM

Noroclav Injection is an off-white Suspension for Injection.

4. PACKAGE SIZE

50 ml /100 ml multidose vial.

5. TARGET SPECIES

Cattle and Dogs.

6. INDICATION(S)

Noroclav Injection has a notably broad spectrum of bactericidal activity against the bacteria commonly found in cattle and dogs.

(a) *In vitro* Noroclav Injection is active against a wide range of clinically important bacteria including:
Gram-positive: Staphylococci (including beta-lactamase producing strains), Streptococci, Corynebacteria, Clostridia, *Bacillus anthracis*, *Actinomyces bovis*.
Gram-negative: *Escherichia coli* (including beta-lactamase producing strains), *Salmonella* spp, (including beta-lactamase producing strains), *Campylobacter* spp, *Klebsiella* spp, *Proteus* spp, *Pasteurellae* spp, *Fusobacterium necrophorum*, *Bacteroides* spp (including beta-lactamase producing strains), *Haemophilus* spp, *Moraxella* spp and *Actinobacillus lignieresi.*

(b) Noroclav Injection is indicated for the treatment of diseases including:

In cattle these include:
Respiratory infections
Soft tissue infections (e.g. joint/navel ill, abscesses etc.)
Metritis
Mastitis
In dogs these include:
Respiratory tract infections
Urinary tract infections
Skin and soft tissue infections (e.g. abscesses, pyoderma, anal sacculitis and gingivitis)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The product is indicated for intramuscular administration to cattle and subcutaneous administration to dogs.

The recommended dosage rate of 8.75 mg/kg bodyweight (1 ml per 20 kg bodyweight) daily for 3-5 days.

Shake the vial well before use. Use a completely dry sterile needle and syringe. Swab the septum before removing each dose. After injection, massage the injection site.
The suspension is not suitable for intravenous or intrathecal administration.

8. WITHDRAWAL PERIOD

Cattle must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 42 days from the last treatment.
Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from treated cattle only after 80 hours from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

The product should not be administered to rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in other very small herbivores. Do not use in animals with known hypersensitivity to penicillin or other substances of the beta-lactam group.

Use of the product may occasionally result in pain on injection and/or local tissue reaction.

The product may be used safely in pregnant animals subject to observance of the stated withdrawal periods.

***Operator Warnings**:* 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 sensitised, 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. Wash hands after use.
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.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

Once a vial has been broached the contents should be used within 28 days. At the time of first use insert the date to discard on the label.

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For Animal Treatment Only.

UK Only

POM-V

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16. MARKETING AUTHORISATION NUMBER(S)

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17. MANUFACTURER'S BATCH NUMBER

FURTHER INFORMATION
Resistance to many antibiotics is caused by beta-lactamase enzymes which destroy the antibiotic before it can act on the bacteria themselves. The clavulanic acid in Noroclav Injection counteracts this defence mechanism by inactivating the beta-lactamases, thus rendering the bacteria sensitive to

amoxicillin's rapid bactericidal effect, at concentrations readily attainable in the body.

Clavulanic acid is moisture sensitive. It is very important, therefore, that a completely dry syringe is used when extracting suspension for injection to avoid contaminating the remaining contents of the vial with water.

Contamination will result in distinct beads of dark, brown discolouration corresponding to the introduced water droplets. Material affected in this way should not be used as it may have significantly reduced potency.

Approved: 26 July 2019