PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincoject 10% w/v Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Lincoject is a clear colourless solution for parenteral administration containing 100 mg Lincomycin, as Lincomycin hydrochloride and 9 mg benzyl alcohol, as preservative, per ml.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

Multidose vials of 100 ml.

5. TARGET SPECIES

Dogs, Cats and Pigs

6. INDICATION(S)

In dogs and cats: For the treatment of infections caused by Lincomycin susceptible Gram-positive organisms, particularly streptococci and staphylococci, and certain anaerobic bacteria e.g. *Bacteroides* spp, *Fusobacterium* spp.

Pigs: For the treatment of infections caused by Lincomycin susceptible Gram-positive organisms e.g. staphylococci, streptococci, certain Gram-negative anaerobic organisms e.g. *Serpulina (Treponema) hyodysenteriae, Bacteroides* spp*, Fusobacterium* spp and *Mycoplasma* spp.

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 epidemiological information.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or intravenous administration to dogs and cats.
For intramuscular administration to pigs.

DOGS AND CATS: By intramuscular administration at a dose rate of 22 mg/kg once daily or 11 mg/kg every 12 hours.

Intravenous administration at a dose rate of 11-22 mg/kg one or two times per day by SLOW intravenous injection.

PIGS: Intramuscularly at a dose rate of 4.5-11 mg/kg once daily.

Practice aseptic techniques.

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

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment.
Pigs (Meat): 3 days

9. SPECIAL WARNING(S), IF NECESSARY

Not recommended for use in species other than the dog, cat or pig. Administration to horses, ruminants, rabbits and rodents may result in severe or fatal enterocolitis.

Not to be given to animals with pre-existing monilial infection.

Lincoject is not effective against *Escherichia coli*, *Salmonella* spp, *Enterococcus faecalis* or yeasts.

Administration at higher levels than those recommended in pigs may cause diarrhoea and loose stools.

For administration of dose volumes less than 1.0 ml a suitably calibrated syringe should be used.

When treating groups of pigs, the use of a multiple dose syringe is recommended. To refill the syringe, the use of a draw-off needle is recommended to avoid excessive broaching of the stopper.

USER WARNINGS

Avoid contact with the product. In case of accidental eye or skin contact, wash off the affected area thoroughly with water.

10. EXPIRY DATE

D.O.M.:
Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light
Following withdrawal of the first dose, the product should be used within 28 days.
Discard unused material.
Keep container in outer carton.

12. SPECIFIC 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.

POM-V

To be supplied only on veterinary prescription

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Newry, Co. Down
United Kingdom

DISTRIBUTED BY:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4183

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincoject 10% w/v Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
100 mg Lincomycin, as Lincomycin hydrochloride.
9 mg benzyl alcohol as preservative.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100ml

5. TARGET SPECIES

Dogs, Cats and Pigs

6. INDICATION(S)

Dogs and cats: For the treatment of infections caused by Lincomycin susceptible Gram-positive organisms, particularly streptococci and staphylococci, and certain anaerobic bacteria e.g. *Bacteroides* spp, *Fusobacterium* spp.
Pigs: For the treatment of infections caused by Lincomycin susceptible Gram-positive organisms e.g. staphylococci, streptococci, certain Gram-negative anaerobic organisms e.g. *Serpulina (Treponema) hyodysenteriae, Bacteroides* spp*, Fusobacterium* spp and *Mycoplasma* spp

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or intravenous administration to dogs and cats. For intramuscular administration to pigs.

DOGS AND CATS: By intramuscular administration at a dose rate of 22 mg/kg once daily or 11 mg/kg every 12 hours. Intravenous administration at a dose rate of 11-22 mg/kg one or two times per day by SLOW intravenous injection.

PIGS: Intramuscularly at a dose rate of 4.5-11 mg/kg once daily. Practice aseptic injection techniques.

8. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment. Pigs (meat): 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

Not recommended for use in species other than the dog, cat or pig. Not to be given to animals with pre-existing monilial infection. Not to be used in animals hypersensitive to lincomycin.

USER WARNINGS
Avoid contact with the product. In case of accidental eye or skin contact, wash off the affected area thoroughly with water.

10. EXPIRY DATE

D.O.M.:
B.N.:
EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Following withdrawal of the first dose use the product within 28 days. Discard unused material. Keep container in outer carton.

12. SPECIFIC 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.

POM-V

To be supplied only on veterinary prescription

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Manufactured by:
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed By:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4183

17. MANUFACTURER'S BATCH NUMBER

B.N.:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

Discard Date : _____

PACKAGE LEAFLET FOR:

Lincoject 10% w/v Solution for Injection

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

Norbrook Laboratories Limited
Newry, Co. Down
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincoject 10% w/v Solution for Injection

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

Lincoject is a clear colourless solution for parenteral administration containing 100 mg Lincomycin, as Lincomycin hydrochloride and 9 mg benzyl alcohol, as preservative, per ml.

4. INDICATION(S)

In dogs and cats: For the treatment of infections caused by Lincomycin susceptible Gram-positive organisms, particularly streptococci and staphylococci, and certain anaerobic bacteria e.g. *Bacteroides* spp, *Fusobacterium* spp.

Pigs: For the treatment of infections caused by Lincomycin susceptible Gram-positive organisms e.g. staphylococci, streptococci, certain Gram-negative anaerobic organisms e.g. *Serpulina (Treponema) hyodysenteriae, Bacteroides* spp*, Fusobacterium* spp and *Mycoplasma* spp.

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 epidemiological information.

5. CONTRAINDICATIONS

Not recommended for use in species other than the dog, cat or pig. Administration to horses, ruminants, rabbits and rodents may result in severe or fatal enterocolitis

Not to be given to animals with pre-existing monilial infection.

Lincoject is not effective against *Escherichia coli*, *Salmonella* spp, *Enterococcus faecalis* or yeasts.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Administration at higher levels than those recommended in pigs may cause diarrhoea and loose stools.

7. TARGET SPECIES

Dogs, Cats and Pigs

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

For intramuscular or intravenous administration to dogs and cats.
For intramuscular administration to pigs.

DOGS AND CATS: By intramuscular administration at a dose rate of 22 mg/kg once daily or 11 mg/kg every 12 hours.
Intravenous administration at a dose rate of 11-22 mg/kg one or two times per day by SLOW intravenous injection.

PIGS: Intramuscularly at a dose rate of 4.5-11 mg/kg once daily.

Practice aseptic techniques.

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

9. ADVICE ON CORRECT ADMINISTRATION

For administration of dose volumes less than 1.0 ml a suitably calibrated syringe should be used.

When treating groups of pigs, the use of a multiple dose syringe is recommended. To refill the syringe, the use of a draw-off needle is recommended to avoid excessive broaching of the stopper.

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment. Pigs (Meat): 3 days

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light
Keep out of the reach and sight of children.
Following withdrawal of the first dose used, the product should be used within 28 days.
Discard unused product.
Keep container in outer carton.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Avoid contact with the product. In case of accidental eye or skin contact, wash off the affected area thoroughly with water.

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

October 2022

15. OTHER INFORMATION

DISTRIBUTED BY:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

PACKAGING QUANTITIES:
Multidose vials of 100 ml.

ManA 2000
Vm: 02000/4183

BN:
D.O.M:
Exp:

Legal Category:

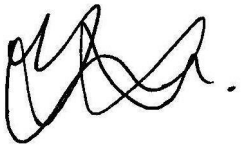
POM-V

To be supplied only on veterinary prescription

FOR ANIMAL TREATMENT ONLY

UK AUTHORISED VETERINARY

LOGO



Approved: 28 October 2022