

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincocin™ Sterile Solution 100 mg/ml Sterile Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml contains 100 mg lincomycin (as lincomycin hydrochloride) plus 9 mg benzyl alcohol as preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs, dogs & cats

6. INDICATION(S)

Antibiotic.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or intravenous use in dogs and cats.

For intramuscular use in pigs.

For full instructions and warnings, see package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs (meat) – 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

For full instructions and warnings, see package leaflet before use.

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze.

Avoid introduction of contamination during use. Discard contents within 21 days of first use.

Keep the container in the outer carton.

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

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

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

1st Floor, Birchwood Building

Springfield Drive

Leatherhead

Surrey

KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4079

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Folding carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincocin™ Sterile Solution 100 mg/ml Sterile Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml contains 100 mg lincomycin (as lincomycin hydrochloride), plus 9 mg benzyl alcohol as preservative.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs, dogs & cats

6. INDICATION(S)

Antibiotic.

Dogs and cats: For the treatment of infections caused by lincomycin-susceptible Gram-positive organisms, particularly Streptococci and Staphylococci, and certain Gram-negative anaerobic organisms e.g. *Bacteroides* spp. or *Fusobacterium* spp.

Pigs: For the treatment of infections caused by lincomycin-susceptible Gram-positive organisms, particularly Streptococci, Staphylococci, and 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 use in dogs and cats.

For intramuscular use in pigs.

Dogs and cats: Intramuscular.

22 mg/kg bodyweight i.m. once daily or 11 mg/kg every 12 hours.

Intravenous: 11-22 mg/kg bodyweight one or two times per day by slow intravenous injection.

Pigs: 4.5-11 mg/kg bodyweight i.m. once daily.

See package leaflet for further details.

8. WITHDRAWAL PERIOD

Pigs (meat) – 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

Practice aseptic injection techniques.

Not recommended for use in species other than dog, cat or pig. Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants as this could result in severe gastro-intestinal disturbance.

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

Not effective against *Escherichia coli*, *Salmonella* spp., *Enterococcus faecalis* or yeasts.

Not to be used in animals hypersensitive to lincomycin.

Higher levels of dosage than recommended may cause diarrhoea and loose stools in pigs.

Clinical antagonism may exist between lincomycin and erythromycin and concurrent use is therefore not recommended.

Operator warnings:

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

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze.

Avoid introduction of contamination during use. Discard contents within 21 days of first use.

Once broached, use by:

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

POM-V

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

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KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4079

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET FOR: Lincocin Sterile Solution 100 mg/ml Sterile Solution for Injection

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

Zoetis UK Limited

1st Floor, Birchwood Building

Springfield Drive

Leatherhead

Surrey

KT22 7LP

Batch release site not currently stated

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincocin™ Sterile Solution 100 mg/ml Sterile Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

A clear colourless sterile solution for injection. Each 1 ml contains lincomycin 100 mg (as lincomycin hydrochloride), plus 9 mg benzyl alcohol as preservative.

4. INDICATIONS

Antibiotic.

Dogs and cats: For the treatment of infections caused by lincomycin susceptible Gram-positive organisms, particularly streptococci and staphylococci, and certain anaerobic organisms e.g. Bacteroides, Fusobacterium spp.

Tonsillitis, laryngitis and other upper respiratory tract infections: Lincocin Sterile Solution has proved effective against most causal organisms.

Abscesses, infected wounds and purulent dermatitis: Lincocin Sterile Solution has proved useful in clearing dermal infection since it readily penetrates tissues and maintains its action in the presence of purulent material.

Septicaemia: Lincocin Sterile Solution has been used successfully to combat septicaemic conditions caused by organisms sensitive to lincomycin.

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*, *Fusobacterium* spp. and *Mycoplasma* spp.

Swine dysentery: Lincocin Sterile Solution has been found effective in the treatment of swine dysentery. Lincocin Sterile Solution may be used in the inappetent pig when 1-2 injections with a 24 hour interval given intramuscularly at a dose of 10 mg/kg will normally be adequate to return the appetite. Follow up treatment should be provided using Lincocin™ Premix or via the drinking water using Lincocin™ Soluble Powder.

Enzootic or mycoplasmal pneumonia: Lincocin Sterile Solution has antimycoplasmal activity, and will provide an effective aid in the treatment of primary infective organisms and the secondary Gram-positive pathogens.

Septic arthritis, foot abscesses: Where these conditions are caused by staphylococci, streptococci, erysipelothrix and mycoplasma sensitive to lincomycin, this antibiotic provides useful treatment by virtue of its ability to penetrate relatively avascular tissue (e.g. joints) and remain active in the presence of purulent material.

5. CONTRAINDICATIONS

This antibiotic is not effective against *E.coli*, *Salmonella* spp, *Enterococcus faecalis* or yeasts.

Not to be used in animals hypersensitive to lincosamides.

Not recommended for use in species other than dog, cat or pig. Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants as this could result in severe gastro-intestinal disturbance.

Lincocin Sterile Solution should not be given to animals with a known pre-existing monilial infection.

6. ADVERSE REACTIONS

The intramuscular administration of Lincocin Sterile Solution to pigs at higher levels than recommended may result in diarrhoea and loose stools.

7. TARGET SPECIES

Dogs, cats and pigs

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dogs and cats: Intramuscularly: 22 mg/kg of bodyweight (given by 1 ml per 4.5 kg bwt) once daily or 11 mg/kg (given by 1 ml per 9 kg bodyweight) every 12 hours.

Intravenously: 11-22 mg/kg bodyweight (given by 1 ml per 9-4.5 kg bwt) one or two times per day by **slow** intravenous injection.

Pigs: Intramuscularly: 4.5-11 mg/kg bodyweight (given by 1 ml 22-9 kg bwt) once daily for a maximum of 3 days.

9. ADVICE ON CORRECT ADMINISTRATION

When the intravenous route is to be used in the dog or cat, administration must be slow.

When injecting large volumes, a maximum of 10 mls per injection site should be administered. It is recommended that no more than two injections per day are given. At the lowest dose rate of 4.5 mg/kg, the maximum recommended weight of animal for treatment is therefore 445 kg and at the higher dose rate of 11 mg/kg, the maximum weight of animal for treatment will be 180 kg.

Practice aseptic injection techniques.

10. WITHDRAWAL PERIOD(S)

Pigs (meat) – 3 days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Do not freeze. Avoid the introduction of contamination during use. Discard contents within 21 days of first use.

When the container is broached for the first time, using the in-use shelf-life which is specified above, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the carton.

12. SPECIAL WARNINGS

Clinical antagonism may exist between lincomycin and erythromycin and concurrent use is therefore not recommended.

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

Keep out of the sight and reach of children.

For animal treatment only.

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 2020

15. OTHER INFORMATION

Lincocin is rapidly absorbed, peak serum levels being reached in 10 minutes to 2 hours following intramuscular injection.

Lincocin Sterile Solution is supplied in 50 ml and 100 ml multidose vials. Not all pack sizes may be marketed.

POM-V

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Vm 42058/4079

Approved 04 September 2020

