

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
50 ML AND 100 ML VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 200 mg/ml solution for injection for Cattle, Sheep and Pigs
Oxytetracycline

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Active substance
Oxytetracycline 200 mg
(Equivalent to Oxytetracycline Dihydrate 216 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Cattle, Sheep and Pigs.

6. INDICATION(S)

Alamycin LA is specifically formulated to provide a prolonged action resulting in sustained antibacterial activity. Blood levels persist for at least 4 days. After administration by the intramuscular route maximum blood levels are achieved after 4 to 8 hours making Alamycin LA suitable for the treatment of acute infections. Oxytetracycline has been shown to be effective *in vitro* against the species:

Bordetella bronchiseptica, Trueperella pyogenes, Erysipelothrix rhusiopathiae, Escherichia coli, Haemophilus somnus, Mannheimia haemolytica, Pasteurella multocida, Salmonella dublin, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus faecalis, Streptococcus pyogenes and Streptococcus uberis.

Alamycin LA is indicated for use in cattle, sheep and pigs in the treatment of: atrophic rhinitis caused by *Bordetella bronchiseptica*, *Mannheimia haemolytica* and *Pasteurella multocida*; navel/joint ill caused by *Arcanobacterium pyogenes*, *E. coli*, and *Staphylococcus aureus*; mastitis caused by *Arcanobacterium pyogenes*, *E. coli*, *Staphylococcus aureus*, *Streptococcus agalactiae*, and *Streptococcus uberis*; metritis caused by *E. coli* and *Streptococcus pyogenes*; pasteurellosis and infections of the respiratory tract caused by *Mannheimia haemolytica* and *Pasteurella multocida*;

septicaemia caused by *Salmonella dublin* and *Streptococcus pyogenes*; erysipelas caused by *Erysipelothrix rhusiopathiae*.

Alamycin LA can also be used in the control of enzootic abortion in sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The recommended dosage rate is 20 mg/kg bodyweight (1 ml per 10 kg bodyweight) by deep intramuscular injection. The product is recommended for a single administration only. Maximum recommended dose at any one site:

Cattle: 20ml
Pigs: 10ml
Sheep: 5ml
Piglets: 1 day 0.2ml
7 days 0.3ml
14 days 0.4ml
21 days 0.5ml
over 21 days 1.0ml/10kg

Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Cattle: Meat and offal – 41 days
Milk – 8 days

Sheep: Meat and offal – 24 days
Milk – 7 days

Pigs: Meat and offal – 20 days

9. SPECIAL WARNING(S), IF NECESSARY

Alamycin LA is not for use in horses, dogs and cats.
Do not dilute Alamycin LA.

Local reactions at the injection site may occur. Collapse has been reported with tetracyclines in weak or debilitated animals. Other adverse reactions to oxytetracycline that have been observed include gastrointestinal disorders and, less frequently, allergic and photosensitivity reactions. In very rare cases, hypersensitivity, allergic or anaphylactic type reactions may occur. If such reactions occur, appropriate treatment is recommended.

Not for use in animals suffering from renal or hepatic damage. The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration. If concurrent treatment is administered, use a separate injection site.

Operator warnings

Wash hands after use. In case of contact with eyes or skin, wash immediately with water as irritation may occur.

Take care to avoid accidental injection.

10. EXPIRY DATE

EXP: {month/year}

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 the container in the outer carton.

When the container is broached for the first time, the date on which any product remaining in the container should be calculated using the in-use shelf-life. This discard date should be written in the space provided on the primary label.

When the vial has been broached and the contents exposed to air, the solution may darken but the potency will be unchanged.

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

Dispose of waste material in accordance with local requirements.

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

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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

Distributed by:

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

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4117

17. MANUFACTURER’S BATCH NUMBER

B.N.:

LOGO

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100ML VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 200 mg/ml solution for injection for Cattle, Sheep and Pigs
Oxytetracycline

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Active substance
Oxytetracycline 200 mg
(Equivalent to Oxytetracycline Dihydrate 216 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, Sheep and Pigs.

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM

Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Withdrawal periods
Cattle: Meat and offal – 41 days; Milk – 8 days
Sheep: Meat and offal – 24 days; Milk – 7 days
Pigs: Meat and offal – 20 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Operator Warnings:

Wash hands after use. In case of contact with eyes or skin, wash immediately with water as irritation may occur.

Take care to avoid accidental injection.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

When the vial has been broached and the contents exposed to air, the solution may darken but the potency will be unchanged.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Protect from light

Keep the container in the outer carton

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

Dispose of waste material in accordance with local requirements.

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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

Distributed by:

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

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4117

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

Once broached, use by: / /

A handwritten signature in black ink, consisting of several vertical strokes followed by a long, sweeping horizontal stroke that curves upwards at the end.

Approved 28 October 2022

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
50ML VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 200 mg/ml solution for injection for Cattle, Sheep and Pigs
Oxytetracycline

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Active substance
Oxytetracycline 200 mg
(Equivalent to Oxytetracycline Dihydrate 216 mg)

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

IM

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle: Meat and offal – 41 days; Milk – 8 days
Sheep: Meat and offal – 24 days; Milk – 7 days
Pigs: Meat and offal – 20 days.

6. BATCH NUMBER

B.N.:
DOM:

7. EXPIRY DATE

EXP: {month/year}

Once broached, use by: / /

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

POM-V

To be supplied only on veterinary prescription

For animal treatment only.

9. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT25 6QQ
Co. Down
Northern Ireland

10. MARKETING AUTHORISATION NUMBER

Vm 02000/4117

PACKAGE LEAFLET:

ALAMYCIN LA 200 MG/ML 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
Station Works
Camlough
Road Newry
Co. Down
BT35 6JP
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 200 mg/ml solution for injection for Cattle, Sheep and
Pigs Oxytetracycline

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

Each ml contains

Active substance
Oxytetracycline 200 mg
(Equivalent to Oxytetracycline Dihydrate 216 mg)

Excipients
Sodium Formaldehyde Sulfoxylate (2 mg)

A clear amber solution for injection.

4. INDICATION(S)

Alamycin LA is specifically formulated to provide a prolonged action resulting in sustained antibacterial activity. Blood levels persist for at least 4 days. After administration by the intramuscular route maximum blood levels are achieved after 4 to 8 hours making Alamycin LA suitable for the treatment of acute infections. Oxytetracycline has been shown to be effective in vitro against the following bacterial species:

Bordetella bronchiseptica, Trueperella pyogenes, Erysipelothrix rhusiopathiae, Escherichia coli, Haemophilus somnus, Mannheimia haemolytica, Pasteurella multocida, Salmonella 10ublin, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus faecalis, Streptococcus pyogenes and Streptococcus uberis.

Alamycin LA is indicated for use in cattle, sheep and pigs in the treatment of: atrophic rhinitis caused by *Bordetella bronchiseptica*, *Mannheimia haemolytica* and *Pasteurella multocida*; navel/joint ill caused by *Arcanobacterium pyogenes*, *E. coli*,

and *Staphylococcus aureus*; mastitis caused by *Arcanobacterium pyogenes*, *E. coli*, *Staphylococcus aureus*, *Streptococcus agalactiae*, and *Streptococcus uberis*; metritis caused by *E. coli* and *Streptococcus pyogenes*; pasteurellosis and infections of the respiratory tract caused by *Mannheimia haemolytica* and *Pasteurella multocida*; septicaemia caused by *Salmonella 11ublin* and *Streptococcus pyogenes*; erysipelas caused by *Erysipelothrix rhusiopathiae*.

Alamycin LA can also be used in the control of enzootic abortion in sheep.

5. CONTRAINDICATIONS

Alamycin LA is not for use in horses, dogs and cats.

Not for use in animals suffering from renal or hepatic damage.

6. ADVERSE REACTIONS

Local reactions at the injection site may occur.

Collapse has been reported with tetracyclines in weak or debilitated animals. Other adverse reactions to oxytetracycline that have been observed include gastrointestinal disorders and, less frequently, allergic and photosensitivity reactions. In very rare cases, hypersensitivity, allergic or anaphylactic type reactions may occur. If such reactions occur, appropriate treatment is recommended.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, sheep and pigs.

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

The recommended dose rate is 20 mg/kg bodyweight (i.e. 1 ml per 10 kg bodyweight) administered by deep intramuscular injection. The product is recommended for a single administration only.

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

Maximum recommended dose at any one site:

Cattle :	20ml
Pigs :	10ml
Sheep:	5ml
Piglets:	1 day 0.2ml
	7 days 0.3ml
	14 days 0.4ml
	21 days 0.5ml
	Over 21 days 1.0 ml/10kg

9. ADVICE ON CORRECT ADMINISTRATION

The product is recommended for a single administration only.

10. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal – 41 days
Milk – 8 days

Sheep: Meat and offal – 24 days
Milk – 7 days

Pigs: Meat and offal – 20 days

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf life after first opening the container: 28 Days

When the container is broached for the first time, the date on which any product remaining in the container should be calculated using the in-use shelf-life. This discard date should be written in the space provided on the primary label.

When the vial has been broached and contents exposed to air, the solution may darken but the potency will be unchanged.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Do not dilute Alamycin LA.

If concurrent treatment is administered, use a separate injection site.

Resistance against oxytetracycline may vary. Use of the product should be based on susceptibility testing and taking into account official and local antimicrobial policies.

Inappropriate use of the product may increase the prevalence of bacteria resistant to oxytetracycline and may decrease the effectiveness of treatment with tetracyclines due to the potential for cross resistance.

Oxytetracycline may interfere with the action of bactericidal antimicrobials, such as penicillins and cephalosporins, and therefore they should not be used simultaneously. Concomitant vaccination is not recommended because of possible immuno- suppressive activity of tetracyclines.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This product may cause hypersensitivity reactions (allergy). Persons with a known hypersensitivity to tetracyclines should not handle this product.

Wash hands after use. In case of contact with eyes or skin, wash immediately with water as irritation may occur.

Take care to avoid accidental injection.

Pregnancy:

The use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration.

Overdose (symptoms, emergency procedures, antidotes):

There is no known specific antidote, if signs of possible overdose occur, treat the animal symptomatically.

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
BT35 6QQ
Co. Down
Northern Ireland

Package Quantities:

Multidose vials of 50 ml and 100 ml.

Not all pack sizes may be marketed.

Further Information:

ManA 2000

Vm 02000/4117

POM-V

To be supplied only on veterinary prescription

FOR ANIMAL TREATMENT ONLY

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LOGO

Approved: