PARTICULARS TO APPEAR ON THE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 300 Solution for Injection 300 mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A sterile aqueous solution containing Oxytetracycline Dihydrate equivalent to 30.00% w/v of oxytetracycline base and Sodium Formaldehyde Sulphoxylate Anhydrous 0.4% w/v.

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml / 250ml / 500ml

5. TARGET SPECIES

Cattle, Sheep Pigs

6. INDICATION(S)

Alamycin LA 300 Solution for Injection 300 mg/ml is a broad-spectrum antibiotic indicated for use in the treatment of conditions caused by, or associated with, organisms sensitive to oxytetracycline in cattle, sheep and pigs. A wide range of Gram-positive and Gram-negative bacteria, including *Bordetella bronchiseptica, Actinomyces pyogenes, Erysipelothrix rhusiopathiae, Pasteurella spp, Staphylococcus* spp and *Streptococcus* spp are sensitive to oxytetracycline. Certain mycoplasma, rickettsiae, protozoa and chlamydia are also sensitive to oxytetracycline.

Alamycin LA 300 Solution for Injection 300 mg/ml may be used in the treatment and control of a wide range of common systemic, respiratory, urinary and local infections caused by oxytetracycline sensitive organisms. Specific indications for Alamycin LA 300 Solution for Injection 300 mg/ml would therefore include: pasteurellosis, pneumonia, atrophic rhinitis, erysipelas, joint-ill/navel ill, summer mastitis in cows, ovine keratoconjunctivitis (pink-eye) and the control of enzootic abortion in sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Alamycin LA 300 Solution for Injection 300 mg/ml is specifically formulated to provide a prolonged action, resulting in sustained antibacterial activity. Following intramuscular administration effective blood levels persist for 3 - 4 days at a dose rate of 20 mg/kg and for 5 - 6 days at a dose rate of 30 mg/kg. Maximum blood

levels are achieved between 4 - 6 hours following administration making Alamycin LA 300 Solution for Injection 300 mg/ml suitable for the treatment of acute infections.

Administer by deep intramuscular injection to cattle, sheep and pigs for the treatment and control of conditions caused by organisms sensitive to the action of oxytetracycline. Swab the septum before removing each dose. Use a sterile needle and syringe.

Alamycin LA 300 Solution for Injection 300 mg/ml can be administered at the standard dose of 20 mg/kg in order to obtain 3 to 4 days duration of activity or at the high dose of 30 mg/kg for prolonged duration of activity (i.e. activity maintained for 5 to 6 days).

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

Cattle, sheep and pigs:	Standard Dose	-	20 mg/kg (1 ml/15 kg)
	High Dose	-	30 mg/kg (1 ml/10 kg)

Maximum recommended dosage at one site:

Cattle:	15 ml
Pigs:	10 ml
Sheep:	5 ml
Piglets:	1 Day - 0.2 ml
	7 Days - 0.3 ml
	14 Days - 0.4 ml
	21 Days - 0.5 ml
	Over 21 Days - 1 ml/10 kg

8. WITHDRAWAL PERIOD

Meat: Animals must not be slaughtered for human consumption during treatment.

20 mg/kg dose: Cattle and sheep may be slaughtered for human consumption only after 28 days from the last treatment. Pigs may be slaughtered for human consumption only after 14 days from the last treatment.

30 mg/kg dose: Cattle may be slaughtered for human consumption only after 35 days from the last treatment. Sheep and pigs may be slaughtered for human consumption only after 28 days from the last treatment.

Milk: Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 8 days from the last treatment. Milk for human consumption can be taken from ewes only after 8 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Do not dilute Alamycin LA 300 Solution for Injection 300 mg/ml.
Although Alamycin LA 300 Solution for Injection 300 mg/ml is well tolerated, occasionally a slight local reaction of a transient nature may be observed.
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 use of tetracyclines during the period of tooth and bone development, including late pregnancy, may lead to discolouration.
Oxytetracycline therapy does not completely eliminate chlamydial infection in a flock.

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 of bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
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.

Operator Warnings:
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.
Avoid accidental self-injection.

10. EXPIRY DATE

D.O.M.:
Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from light.
This product does not contain an antimicrobial preservative.

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

When the container is broached for the first time, the date by which any product remaining in the container should be disposed of should be calculated. A statement of the in-use shelf life of the product is given on the package insert. This discard date should be written in the space provided on the primary label.

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

[Distribution category]

For animal treatment only.

POM-V To be supplied only on veterinary prescription

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

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

MANUFACTURED BY:
Norbrook Laboratories Limited Station Works
Newry
BT35 6JP
United Kingdom

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4113

17. MANUFACTURER'S BATCH NUMBER

B.N.:

FURTHER INFORMATION

If stored as directed Alamycin LA 300 Solution for Injection 300 mg/ml can be expected to retain its potency for 2 years from the manufacturing date. When the vial has been broached and the contents exposed to air, the solution may darken but the potency will be unchanged.

PARTICULARS TO APPEAR ON THE 100 ml Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 300 Solution for Injection 300 mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A sterile aqueous solution containing Oxytetracycline Dihydrate equivalent to 30.00% w/v of oxytetracycline base and Sodium Formaldehyde Sulphoxylate Anhydrous 0.4% w/v.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, Sheep, Pigs.

6. INDICATION(S)

For the treatment of conditions caused by or associated with organisms sensitive to oxytetracycline including:
Bordetella bronchiseptica Actinomyces pyogenes Erysipelothrix rhusiopathiae Pasteurella spp *Staphylococcus* spp and *Streptococcus* spp.
Certain mycoplasma, rickettsiae, protozoa and chlamydia are also sensitive to oxytetracycline.
The product is indicated for the treatment and control of pasteurellosis, pneumonia, atrophic rhinitis, erysipelas, joint-ill, navel-ill, summer mastitis in cows, ovine keratoconjunctivitis (pink-eye) and enzootic abortion in sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Alamycin LA 300 Solution for Injection 300 mg/ml can be administered as a single dose either at a dose rate of 20 mg/kg in order to obtain 3 - 4 days duration of activity or 30 mg/kg for prolonged duration of activity (i.e. activity maintained for 5 - 6 days).

Cattle, sheep and pigs:
Standard Dose - 20 mg/kg (1 ml/15 kg)
High Dose - 30 mg/kg (1 ml/10 kg)

Administer by deep intramuscular injection to cattle, sheep and pigs for the treatment and control of conditions caused by or associated with organisms sensitive to oxytetracycline.

8. WITHDRAWAL PERIOD

Meat: Animals must not be slaughtered for human consumption during treatment. 20 mg/kg dose: Cattle and sheep may be slaughtered for human consumption only after 28 days from the last treatment. Pigs may be slaughtered for human consumption only after 14 days from the last treatment. 30 mg/kg dose: Cattle may be slaughtered for human consumption only after 35 days from the last treatment. Sheep and pigs may be slaughtered for human consumption only after 28 days from the last treatment.

Milk: Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 8 days from the last treatment. Milk for human consumption may be taken from ewes only after 8 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Operator warnings:

In case of contact with eyes or skin wash immediately with water as irritation may occur.
Avoid accidental self-injection.
Wash hands after use.

10. EXPIRY DATE

Exp.: dd/mm/yy

Once Broached, discard by: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Protect from light
Following the withdrawal of the first dose, use the product within 28 days.
Discard unused material.
Keep vial in outer carton.
This product does not contain any antimicrobial preservative.

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

[Distribution category]
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 sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4113

17. MANUFACTURER'S BATCH NUMBER

BN.:

D.O.M.:

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

Further Information: See Package Leaflet

PARTICULARS TO APPEAR ON THE 250 mL and 500 mL Base Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 300 Solution for Injection 300 mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

A sterile aqueous solution containing Oxytetracycline Dihydrate equivalent to 30.00% w/v of oxytetracycline base and Sodium Formaldehyde Sulphoxylate Anhydrous 0.4% w/v.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

250 ml/ 500 ml

5. TARGET SPECIES

Cattle, Sheep, Pigs.

6. INDICATION(S)

For the treatment of conditions caused by or associated with organisms sensitive to oxytetracycline including:
Bordetella bronchiseptica Actinomyces pyogenes Erysipelothrix rhusiopathiae Pasteurella spp *Staphylococcus* spp and *Streptococcus* spp.

Certain mycoplasma, rickettsiae, protozoa and chlamydia are also sensitive to oxytetracycline.
The product is indicated for the treatment and control of pasteurellosis, pneumonia, atrophic rhinitis, erysipelas, joint-ill, navel-ill, summer mastitis in cows, ovine keratoconjunctivitis (pink-eye) and enzootic abortion in sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Alamycin LA 300 Solution for Injection 300 mg/ml can be administered as a single dose either at a dose rate of 20 mg/kg in order to obtain 3 - 4 days duration of activity or 30 mg/kg for prolonged duration of activity (i.e. activity maintained for 5 - 6 days).

Cattle, sheep and pigs:
Standard Dose - 20 mg/kg (1 ml/15 kg)
High Dose - 30 mg/kg (1 ml/10 kg)

Administer by deep intramuscular injection to cattle, sheep and pigs for the treatment and control of conditions caused by or associated with organisms sensitive to oxytetracycline.

8. WITHDRAWAL PERIOD

Meat: Animals must not be slaughtered for human consumption during treatment. 20 mg/kg dose: Cattle and sheep may be slaughtered for human consumption only after 28 days from the last treatment. Pigs may be slaughtered for human consumption only after 14 days from the last treatment. 30 mg/kg dose: Cattle may be slaughtered for human consumption only after 35 days from the last treatment. Sheep and pigs may be slaughtered for human consumption only after 28 days from the last treatment. Milk: Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 8 days from the last treatment. Milk for human consumption may be taken from ewes only after 8 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Operator warnings:
In case of contact with eyes or skin wash immediately with water as irritation may occur.
Avoid accidental self-injection.
Wash hands after use.

10. EXPIRY DATE

Exp.: dd/mm/yy
Once Broached, discard by: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Protect from light
Following the withdrawal of the first dose, use the product within 28 days.
Discard unused material.
Keep vial in outer carton.
This product does not contain any antimicrobial preservative.

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 sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4113

17. MANUFACTURER'S BATCH NUMBER

BN.:
D.O.M.:

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

Further Information: See Expanding Label

PARTICULARS TO APPEAR ON THE 250 mL and 500 mL Expanding Label

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
Newry
Co. Down
BT35 6JP
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 300 Solution for Injection 300 mg/ml

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

A sterile aqueous solution containing Oxytetracycline Dihydrate equivalent to 30.00% w/v of oxytetracycline base and Sodium Formaldehyde Sulphoxylate Anhydrous 0.4% w/v.

4. INDICATION(S)

Alamycin LA 300 Solution for Injection 300 mg/ml is a broad spectrum antibiotic indicated for use in the treatment of conditions caused by, or associated with, organisms sensitive to oxytetracycline in cattle, sheep and pigs. A wide range of Gram-positive and Gram-negative bacteria, including *Bordetella bronchiseptica*, *Actinomyces pyogenes*, *Erysipelothrix rhusiopathiae, Pasteurella* spp, *Staphylococcus* spp and *Streptococcus* spp are sensitive to oxytetracycline. Certain mycoplasma, rickettsiae, protozoa and chlamydia are also sensitive to oxytetracycline.

Alamycin LA 300 Solution for Injection 300 mg/ml may be used in the treatment and control of a wide range of common systemic, respiratory, urinary and local infections caused by oxytetracycline sensitive organisms. Specific indications for Alamycin LA 300 Solution for Injection 300 mg/ml would therefore include: pasteurellosis, pneumonia, atrophic rhinitis, erysipelas, joint-ill/navel ill, summer mastitis in cows, ovine keratoconjunctivitis (pink-eye) and the control of enzootic abortion in sheep.

Use of the product should be based on susceptibility testing of bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

5. CONTRAINDICATIONS

Oxytetracycline therapy does not completely eliminate chlamydial infection in a flock.

6. ADVERSE REACTIONS

Although Alamycin LA 300 Solution for Injection 300 mg/ml is well tolerated, occasionally a slight local reaction of a transient nature may be observed. 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
Pigs

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

Alamycin LA 300 Solution for Injection 300 mg/ml is specifically formulated to provide a prolonged action, resulting in sustained antibacterial activity. Following intramuscular administration effective blood levels persist for 3 - 4 days at a dose rate of 20 mg/kg and for 5 - 6 days at a dose rate of 30 mg/kg. Maximum blood levels are achieved between 4 - 6 hours following administration making Alamycin LA 300 Solution for Injection 300 mg/ml suitable for the treatment of acute infections.

Alamycin LA 300 Solution for Injection 300 mg/ml can be administered at the standard dose of 20 mg/kg in order to obtain 3 to 4 days duration of activity or at the high dose of 30 mg/kg for prolonged duration of activity (i.e. activity maintained for 5 to 6 days). Use aseptic injection technique.

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

Cattle, sheep and pigs:	Standard Dose	-	20 mg/kg (1 ml/15 kg)
	High Dose	-	30 mg/kg (1 ml/10 kg)

Maximum recommended dosage at one site:

Cattle: 15 ml
Pigs: 10 ml
Sheep: 5 ml
Piglets: 1 Day - 0.2 ml
7 Days - 0.3 ml
14 Days - 0.4 ml
21 Days - 0.5 ml
Over 21 Days - 1 ml/10 kg

9. ADVICE ON CORRECT ADMINISTRATION

Administer by deep intramuscular injection to cattle, sheep and pigs for the treatment and control of conditions caused by organisms sensitive to the action of oxytetracycline.

Swab the septum before removing each dose. Use a sterile needle and syringe.

10. WITHDRAWAL PERIOD(S)

Meat: Animals must not be slaughtered for human consumption during treatment.

20 mg/kg dose: Cattle and sheep may be slaughtered for human consumption only after 28 days from the last treatment. Pigs may be slaughtered for human consumption only after 14 days from the last treatment.
30 mg/kg dose: Cattle may be slaughtered for human consumption only after 35 days from the last treatment. Sheep and pigs may be slaughtered for human consumption only after 28 days from the last treatment.

Milk: Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 8 days from the last treatment. Milk for human consumption may be taken from ewes only after 8 days from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC. Protect from light.
Following withdrawal of the first dose use the product within 28 days. Discard unused material.
Keep out of sight and reach of children.
When the container is broached for the first time, the date by which any product remaining in the container should be disposed of should be calculated. A statement of the in-use shelf life of the product is given on the package leaflet. This discard date should be written in the space provided on the primary label. Keep the vial in outer carton.
This product does not contain any antimicrobial preservative.

12. SPECIAL WARNING(S)

Do not dilute Alamycin LA 300 Solution for Injection 300 mg/ml.
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. Resistance against oxytetracycline may vary.
Use of the product should be based on susceptibility testing of bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. 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.

Operator warnings:

This product may cause hypersensitivity reactions (allergy). Persons with a known hypersensitivity to tetracyclines should not handle this product.
Avoid accidental self-injection. Wash hands after use.
In case of contact with eyes or skin wash immediately with water as irritation may occur.

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

If stored as directed Alamycin LA 300 Solution for Injection 300 mg/ml can be expected to retain its potency for 2 years from the manufacturing date. When the vial has been broached and the contents exposed to air, the solution may darken but the potency will be unchanged.

To be supplied on veterinary prescription only POM-V

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

Package Quantities:
Multi-dose vials of 100 ml, 250ml and 500ml.

BN:
D.O.M:
Exp:

ManA 2000
Vm 02000/4113

FOR ANIMAL TREATMENT ONLY
UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LOGO

PACKAGE LEAFLET

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
Newry
Co. Down, BT35 6JP
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin LA 300 Solution for Injection 300 mg/ml

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

A sterile aqueous solution containing Oxytetracycline Dihydrate equivalent to 30.00% w/v of oxytetracycline base and Sodium Formaldehyde Sulphoxylate Anhydrous 0.4% w/v.

4. INDICATION(S)

Alamycin LA 300 Solution for Injection 300 mg/ml is a broad spectrum antibiotic indicated for use in the treatment of conditions caused by, or associated with, organisms sensitive to oxytetracycline in cattle, sheep and pigs. A wide range of Gram-positive and Gram-negative bacteria, *including Bordetella bronchiseptica, Actinomyces pyogenes, Erysipelothrix rhusiopathiae, Pasteurella* spp, *Staphylococcus* spp and *Streptococcus* spp are sensitive to oxytetracycline. Certain mycoplasma, rickettsiae, protozoa and chlamydia are also sensitive to oxytetracycline.

Alamycin LA 300 Solution for Injection 300 mg/ml may be used in the treatment and control of a wide range of common systemic, respiratory, urinary and local infections caused by oxytetracycline sensitive organisms. Specific indications for Alamycin LA 300 Solution for Injection 300 mg/ml would therefore include: pasteurellosis, pneumonia, atrophic rhinitis, erysipelas, joint-ill/navel ill, summer mastitis in cows, ovine keratoconjunctivitis (pink-eye) and the control of enzootic abortion in sheep.

Use of the product should be based on susceptibility testing of bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

5. CONTRAINDICATIONS

Oxytetracycline therapy does not completely eliminate chlamydial infection in a flock.

6. ADVERSE REACTIONS

Although the product is well tolerated, occasionally a slight local reaction of a transient nature may be observed. 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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle
Sheep
Pigs

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

Alamycin LA 300 Solution for Injection 300 mg/ml is specifically formulated to provide a prolonged action, resulting in sustained antibacterial activity. Following intramuscular administration effective blood levels persist for 3 - 4 days at a dose rate of 20 mg/kg and for 5 - 6 days at a dose rate of 30 mg/kg. Maximum blood levels are achieved between 4 - 6 hours following administration making Alamycin LA 300 Solution for Injection 300 mg/ml suitable for the treatment of acute infections.

Alamycin LA 300 Solution for Injection 300 mg/ml can be administered at the standard dose of 20 mg/kg in order to obtain 3 to 4 days duration of activity or at the high dose of 30 mg/kg for prolonged duration of activity (i.e. activity maintained for 5 to 6 days). Use aseptic injection technique.

Cattle, sheep and pigs:	Standard Dose	- 20 mg/kg (1 ml/15 kg)
	High Dose	- 30 mg/kg (1 ml/10 kg)

Maximum recommended dosage at one site:

Cattle:	15 ml
Pigs:	10 ml
Sheep:	5 ml
Piglets:	1 Day - 0.2 ml
	7 Days - 0.3 ml
	14 Days - 0.4 ml
	21 Days - 0.5 ml
	Over 21 Days - 1 ml/10 kg

9. ADVICE ON CORRECT ADMINISTRATION

Administer by deep intramuscular injection to cattle, sheep and pigs for the treatment and control of conditions caused by organisms sensitive to the action of oxytetracycline.

Swab the septum before removing each dose. Use a sterile needle and syringe.

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

10. WITHDRAWAL PERIOD(S)

Meat: Animals must not be slaughtered for human consumption during treatment.

20 mg/kg dose: Cattle and sheep may be slaughtered for human consumption only after 28 days from the last treatment. Pigs may be slaughtered for human consumption only after 14 days from the last treatment.

30 mg/kg dose: Cattle may be slaughtered for human consumption only after 35 days from the last treatment. Sheep and pigs may be slaughtered for human consumption only after 28 days from the last treatment.

Milk: Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cows only after 8 days from the last treatment. Milk for human consumption may be taken from ewes only after 8 days from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Do not store above 25ºC.
Protect from light.
Following withdrawal of the first dose use the product within 28 days. Discard unused material.
This product does not contain an antimicrobial preservative.
When the container is broached for the first time, the date on which any product remaining in the container should be calculated. A statement of the in-use shelf life of

the product is given on the package leaflet. This discard date should be written in the space provided on the primary label.
Keep vial in outer carton.

12. SPECIAL WARNING(S)

Do not dilute Alamycin LA 300 Solution for Injection 300 mg/ml.
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

This product may cause hypersensitivity reactions (allergy). Persons with a known hypersensitivity to tetracyclines should not handle this product.
Avoid accidental self-injection.
Wash hands after use. In case of contact with eyes or skin wash immediately with water as irritation may occur.
Resistance against oxytetracycline may vary.
Use of the product should be based on susceptibility testing of bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
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.

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

To be supplied only by veterinary prescription For Animal Treatment Only

PACKAGE QUANTITIES

Multi-dose vials of 100 ml, 250ml and 500ml.

Not all package sizes may be presented.

FURTHER INFORMATION

If stored as directed Alamycin LA 300 Solution for Injection 300 mg/ml can be expected to retain its potency for 2 years from the manufacturing date. When the vial has been broached and the contents exposed to air, the solution may darken but the potency will be unchanged.

MARKETING AUTHORISATION NUMBER

ManA: 2000
Vm 02000/4113

DISTRIBUTED BY

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

Approved 28 October 2022