PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alamycin 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
100 mg Oxytetracycline Hydrochloride, plus 1.5 mg sodium formaldehyde sulphoxylate dihydrate as antioxidant.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml and 100 ml vials

5. TARGET SPECIES

Cattle and Pigs.

6. INDICATION(S)

For the treatment of diseases caused by or associated with organisms sensitive to oxytetracycline in cattle and pigs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By intramuscular or slow intravenous injection.

Cattle: 1.5 - 4.0 mg/kg bodyweight daily for 3 to 5 days
Pigs: 2.0 - 9.0 mg/kg bodyweight daily for 3 to 5 days

Maximum dose volume for cattle should not exceed 10 ml per site.
Maximum dose volume in pigs should not exceed 5 ml per site.

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

Pictogram of cow: For a 500kg cow 1.5-4.0 mg/kg (7.5ml-20ml)
Pictogram of pig: For a 150 kg pig 2.0-9.0 mg/kg (3.0ml-13.5ml)

8. WITHDRAWAL PERIOD

Cattle:
Meat & Offal: 16 days

Milk: 84 hours
Pigs:
Meat & Offal: 11 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.
Protect from light.
Following withdrawal of the first dose, use the product within 28 days.
Once broached, use by: ___/___/___
Discard unused material.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

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

Manufacturer:
Norbrook Laboratories Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby

Northamptonshire
NN18 9EX
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4037

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PACKAGE LEAFLET FOR:

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
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALAMYCIN 100 mg/ml SOLUTION FOR INJECTION

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

A stable aqueous solution for injection containing Oxytetracycline Hydrochloride 100 mg/ml, plus 1.5 mg/ml sodium formaldehyde sulphoxylate dihydrate as antioxidant.

4. INDICATION(S)

For the treatment of diseases caused by or associated with organisms sensitive to oxytetracycline in cattle and pigs.

5. CONTRAINDICATIONS

Do not use in animals suffering from renal or hepatic damage. Do not use in animals with known hypersensitivity to oxytetracycline or any of the excipients.

6. ADVERSE REACTIONS

Side effects of oxytetracycline have been observed, including gastrointestinal disorders and, less frequently, allergic and photosensitivity reactions. Tooth discoloration may result if given to young animals.
General toxicity is low although collapse has been reported with tetracycline in weak or debilitated animals.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and Pigs

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

By intramuscular or slow intravenous injection.

Cattle: 1.5 – 4.0 mg/kg bodyweight daily.
Pigs: 2.0 – 9.0 mg/kg bodyweight daily.

Maximum dose volume for cattle should not exceed 10 ml per site.
Maximum dose volume for pigs should not exceed 5ml per site.

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

9. ADVICE ON CORRECT ADMINISTRATION

Take care to avoid accidental injection. Wash hands after use. In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur.

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat & Offal: 16 days
Milk: 84 hours
Pigs:
Meat & Offal: 11 days

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC.
Protect from light.
Keep out of the sight and reach of children.
Following withdrawal of the first dose, use the product within 28 days. Discard unused material.
When the container is broached (opened) for the first time, the date on which any product remaining in the container should be discarded 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 label.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
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 (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official and local antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to oxytetracycline.
It is important to administer intravenous injections of the product slowly.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Take care to avoid accidental injection.
Wash hands after use.
In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur.

Pregnancy:
The use of tetracycline during the period of tooth development, including late pregnancy may lead to tooth discoloration. Oxytetracycline can retard skeletal growth of the fetus if administered during pregnancy.

Lactation:
Tetracyclines are excreted in milk. The product should only be used according to the benefit/ risk assessment by the responsible veterinary surgeon.

Overdose (symptoms, emergency procedures, antidotes):
There is no known specific antidote. If signs of possible overdose occur, treat the animal symptomatically.

Interaction with other medicinal products and other forms of interaction:
Dilution with calcium salts will cause precipitation and should be avoided.
Oxytetracycline may interfere with the action of bactericidal antimicrobials such as penicillins and cephalosporins and therefore they should not be used simultaneously.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2014

15. OTHER INFORMATION

Distributed by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

Package Quantities:
Multidose vials of 50 ml and 100 ml.

Not all pack sizes may be marketed.

ManA 2000
Vm 02000/4037

POM-V To be supplied only on veterinary prescription

FOR ANIMAL TREATMENT ONLY
UK AUTHORISED VETERINARY MEDICINAL PRODUCT

LOGO

Approved: 14/06/2017