PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare LA Suspension for Injection 15% w/v

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Amoxycillin (as amoxycillin trihydrate) 150 mg.
Also contains: Butylated hydroxyanisole 0.08 mg
Butylated hydroxytoluene 0.08 mg as antioxidant

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

50ml/100ml/250ml/500ml

5. TARGET SPECIES

Cattle, Sheep, Pigs, Dogs and Cats

6. INDICATION(S)

See package leaflet

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle, sheep and pigs: By intramuscular injection only.

Dogs and cats: By subcutaneous or intramuscular injection.

Dose: 15 mg/kg bodyweight (equivalent to 1 ml per 10 kg bodyweight), repeatable if necessary after 48 hours. Massage the injection site. A separate injection site should be used for each administration.

Dose volume is equivalent to 1 ml per 10 kg body weight. If dose volume exceeds 15 ml in cattle and 4 ml in sheep and pigs, it should be divided and injected into two or more sites.

Suggested Dosage:

CATTLE :450 kg - 45.0 ml
SHEEP :65 kg - 6.5 ml
PIGS :150 kg - 15.0 ml
DOGS :20 kg - 2.0 ml
CATS :5 kg - 0.5 ml

8. WITHDRAWAL PERIOD

Cattle:
Meat and offal: 39 days
Milk: 108 hours (4.5 days)

Pigs:
Meat and offal: 42 days

Sheep:
Meat and offal: 29 days
Milk: Not authorised for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

SHAKE WELL BEFORE USE

Occasional local reaction may occur with use of Amoxycare LA.

Penicillin/cephalosporin may occasionally cause severe allergic reactions. See package leaflet for operator warning. Not effective against beta-lactamase producing organisms.

Amoxycillin, like other Penicillins, should not be administered orally or parenterally in rabbits, hamsters, gerbils and guinea pigs.

Not suitable for intravenous or intrathecal administration.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Following withdrawal of the first dose use the product within 28 days. Discard unused material. This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe.
Do not store above 25ºC. Protect from light.

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4141

17. MANUFACTURER'S BATCH NUMBER

Bn.:
D.O.M.:

Further Information: See package Leaflet.

Distributed by:
Animalcare Ltd
10 Great North Way
York
YO26 6RB

PACKAGE LEAFLET FOR:

Amoxycare LA Suspension for Injection 15% w/v

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

Amoxycare LA Suspension for Injection 15% w/v

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

Amoxycare LA Injection is an off white sterile suspension containing 150 mg/ml amoxicillin as amoxicillin trihydrate. Chemically, amoxicillin is 6[D(-) - ∝- amino-p-hydroxy-phenylacetamido] penicillanic acid.

Also contains Butylated hydroxyanisole 0.08 mg/ml and butylated hydroxytoluene 0.08 mg/ml as antioxidant.

4. INDICATION(S)

Amoxicillin is a broad-spectrum semi-synthetic penicillin bactericidal in action for use in cattle, pigs, sheep, dogs and cats. *In vitro* it is effective against a wide range of Gram-positive and Gram-negative bacteria which include: *Escherichia coli, Klebsiella pneumoniae, Proteus* species*, Salmonella* species*, Staphylococci* and *Streptococci.*

This product is not effective against beta-lactamase producing organisms.

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.

Amoxycare LA Injection is suitable for the control of infections, due to susceptible micro-organisms, in cattle, sheep, pigs, dogs and cats where a single injection giving prolonged activity is required. It may also protect from secondary bacterial invasion due to sensitive organisms in cases where bacteria are not the initial cause of the disease.

Indications include infections of:
(a) Alimentary tract
(b) Respiratory tract
(c) Skin and soft tissue
(d) Urogenital tract and
(e) In prevention of post-operative infection (treat before surgery)

5. CONTRAINDICATIONS

Not effective against beta-lactamase producing organisms.

Amoxicillin, like other penicillins, should not be administered orally or parenterally in rabbits, hamsters, gerbils and guinea pigs.

Not for use in known cases of hypersensitivity to penicillins or cephalosporins.

6. ADVERSE REACTIONS

In rare cases, hypersensitivity reactions such as urticaria anaphylaxis shock can occur after use. In the case of allergic reactions, treatment should be discontinued and a symptomatic treatment should be initiated. In very rare cases, local tissue reactions such as swelling and pruritus may result from the use of amoxicillin.

The frequency of adverse reactions is defined using the following convention:
- 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, Dogs and Cats

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

Cattle, sheep and pigs : By intramuscular injection only.
Dogs and cats : By subcutaneous or intramuscular injection.

The recommended dosage rate is 15 mg per kg bodyweight, repeatable if necessary after 48 hours. Massage the injection site. A separate injection site should be used for each administration. Swab the septum before removing each dose. Use a dry, sterile needle and syringe.

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

ANIMAL	WEIGHT (kg)	DOSAGE VOLUME (ml)
Cattle	450 kg	45.0 ml
Sheep	65 kg	6.5 ml
Pig	150 kg	15.0 ml
Dog	20 kg	2.0 ml
Cat	5 kg	0.5 ml

Dose volume is equivalent to 1 ml per 10 kg body weight. If dose volume exceeds 15 ml in cattle and 4 ml in sheep and pigs, it should be divided and injected into two or more sites.

If no distinct clinical response is seen after the second treatment, a check of the diagnosis and eventually a change of treatment are required.

9. ADVICE ON CORRECT ADMINISTRATION

As with other injectable preparations, normal aseptic precautions should be observed as this product does not contain antimicrobial preservative. (Use dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin). Massage the injection site.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 39 days
Milk: 108 hours (4.5 days)

Pigs:
Meat and offal: 42 days

Sheep:
Meat and offal: 29 days
Milk: Not authorised for use in sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

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

Shake well before use. 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 (opened) for the first time, using the in-use shelf-life which is specified on this package insert, 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 label.

12. SPECIAL WARNING(S)

This product is not suitable for intravenous or intrathecal administration.

Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact.

Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

2. Handle this product with great care to avoid exposure taking all recommended precautions.

3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hand after use.

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

Dispose of any unused product and empty container in accordance with guidance from your local waste regulatory authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2022

15. OTHER INFORMATION

LEGAL CATEGORY:

POM-V

To be supplied only on veterinary prescription

PACKAGE QUANTITIES:

50 ml and 100 ml multidose glass vials.
50 ml, 100ml, 250 ml and 500 ml PET plastic vials.

FURTHER INFORMATION:

Due to its wide distribution, after absorption, high levels of amoxicillin are found in kidney, urine, liver and bile.

Also important is the rapid bactericidal action.

Due to its mode of action amoxicillin prevents recrudescence of respiratory infections. The absence of toxicity, shared with other penicillins, is also apparent.

Animals with functional rumens should only be treated parenterally.

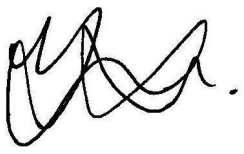
MARKETING AUTHORISATION NUMBER:

Vm 02000/4141

DISTRIBUTED BY:

Animalcare Ltd
10 Great North Way
York
YO26 6RB

FOR ANIMAL TREATMENT ONLY



Approved: 01 March 2022