PARTICULARS TO APPEAR ON THE OUTER PACKAGE

50/100ML LABEL – PLASTIC & GLASS VIALS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxycare Suspension for Injection 15% w/v

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Amoxicillin (as amoxicillin trihydrate) 150 mg. Also contains: Butylated hydroxyanisole 0.08 mg/ml and butylated hydroxytoluene 0.08 mg/ml, as antioxidants.

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

50/100ml

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.

Dosage Rate: 7 mg per kg bodyweight for up to five days (equivalent 0.25 ml per 5 kg daily). The injection site should be massaged. A separate injection site should be used for each administration.

Suggested Doses:

CATTLE	450 kg - 20.0 ml
SHEEP	65 kg - 3.0 ml
PIGS	150 kg - 7.0 ml
DOGS	20 kg - 1.0 ml

CATS 5 kg - 0.25 ml

Not suitable for intravenous or intrathecal administration

8. WITHDRAWAL PERIOD

Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may only be taken from a cow after 24 hours from the last treatment. Not for use in sheep producing milk for human consumption. Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 18 days from the last treatment. Sheep may be slaughtered for human consumption only after 10 days from the last treatment. Pigs may be slaughtered for human consumption only after 16 days from the last treatment

9. SPECIAL WARNING(S), IF NECESSARY

As with other Penicillins, amoxicillin should not be used in rabbits, hamsters, gerbils or guinea pigs. Not effective against beta-lactamase producing organisms. Occasional local tissue reaction may occur from use of this product. Penicillin/cephalosporin may occasionally cause severe allergic reactions. See package leaflet for operator warning.

Following withdrawal of the first dose, use the product within 28 days. Discard any unused material. This product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry sterile needle and syringe.

SHAKE WELL BEFORE USE

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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(S)

Vm 02000/4140

ManA 2000

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

Once broached, use by:_____

PACKAGE LEAFLET FOR: AMOXYCARE 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 Suspension for Injection 15% w/v

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

Amoxycare Injection is an off-white sterile suspension containing 150 mg/ml amoxicillin as amoxicillin trihydrate. Chemically, amoxicillin is 6 [D (-) - ∝ - amino-p-hydroxyphenylacetamido] penicillanic acid. Also contains: Butylated hydroxyanisole 0.08 mg/ml and butylated hydroxytoluene 0.08 mg/ml, as antioxidants.

4. INDICATION(S)

Amoxycare Injection is a broad spectrum semi-synthetic penicillin, bactericidal in action. *In vitro* it is effective against a wide range of Gram-positive and Gram-negative bacteria which include: *Actinobacillus equuli*, *Actinobacillus lignieresi*, *Actinomyces bovis*, *Bacillus anthracis*, *Bordetella bronchiseptica*, *Clostridium* species, *Corynebacterium* species, *Erysipelothrix rhusiopathiae*, *Escherichia coli*, *Fusiformis* species, *Haemophilus* species, *Moraxella* species, *Pasteurella* species, *Proteus mirabilis*, *Salmonella* species, *Staphylococci* and *Streptococci* in cattle, sheep, pigs, dogs and cats.

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.

5. CONTRAINDICATIONS

Not effective against beta-lactamase producing organisms.

As with other penicillins Amoxicillin should not be used in rabbits, hamsters, gerbils and guinea pigs.

6. ADVERSE REACTIONS

Occasional local tissue reaction may result from use of this product.

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 7 mg/kg bodyweight once a day for up to five days. Massage the injection site.

ANIMAL	WEIGHT (kg)	DOSE VOLUME
Cattle	450 kg	20.0 ml
Sheep	65 kg	3.0 ml
Pigs	150 kg	7.0 ml
Dogs	20 kg	1.0 ml
Cats	5 kg	0.25 ml

(Guide dose volume is equivalent to 0.25 ml per 5 kg daily).

If dose volume exceeds 20 ml in cattle or 10 ml in sheep and pigs, it should be divided and injected into two sites.

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

9. ADVICE ON CORRECT ADMINISTRATION

Shake bottle before use.

Normal aseptic precautions should be observed.

An appropriate graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes. This product is not suitable for administration via intravenous or intrathecal routes.

10. WITHDRAWAL PERIOD(S)

Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may only be taken after 24 hours from the last treatment.

Not for use in sheep producing milk for human consumption.

Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 18 days from the last treatment. Sheep may be slaughtered for human consumption only after 10 days from the last treatment. Pigs may be slaughtered for human consumption only after 16 days from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach of children.

Do not store above 25°C.

12. SPECIAL WARNING(S)

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 penicillin 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 hands after use.

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

July 2013

<15. OTHER INFORMATION>

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.

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

Legal Category:

POM –V	To be supplied only on Veterinary Prescription

Package Quantities:

50 ml and 100 ml multidose glass vials

50ml and 100ml PET plastic vials

Further Information:

High levels of Amoxicillin are found in kidney, urine, liver and bile after absorption due to its wide distribution.

In common with other Penicillins an absence of toxicity is apparent even at high dose levels.

Animals with functional rumens should only be treated parenterally.

Marketing Authorisation Number:

Vm 02000/4140

ManA 2000

Distributed by:

Animalcare Ltd

10 Great North Way

York

YO26 6RB

FOR ANIMAL TREATMENT ONLY Logo

Approved: 31/01/2018