

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphamox LA 150 mg/ml Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Amoxicillin 150 mg as Amoxicillin Trihydrate, Butylated Hydroxyanisole 0.08 mg and Butylated Hydroxytoluene 0.08 mg as antioxidants in a long acting base

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, sheep, pigs, dogs and cats

6. INDICATION(S)

For the treatment of infection caused by or associated with organisms sensitive to amoxicillin. For use: See leaflet

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle, sheep and pigs: by intramuscular injection only. Dogs and cats: by subcutaneous or intramuscular injection. **SHAKE WELL BEFORE USE.** Use a dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin. Massage the site after injection.

Dosage: 1 ml per 10 kg bodyweight. Dose may be repeated after 48 hours.

Cow icon 450 kg – 45 ml

Sheep icon 50 kg – 5 ml

Pig icon 50 kg – 5 ml

Dog icon 10 kg – 1 ml

Cat icon 5 kg – 0.5 ml

8. WITHDRAWAL PERIOD

Cattle - meat and offal: 23 days.

Cattle - milk: 84 hours.

Sheep and pigs - meat and offal: 16 days.

Not for use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in known cases of hypersensitivity to penicillin.

Not suitable for intravenous or intrathecal administration. Not to be used in small herbivores such as rabbits, guinea pigs, gerbils and hamsters. Not effective against penicillinase producing organisms. Occasional local tissue reaction may result from use of this product.

Operator Warning: Penicillins/cephalosporins may occasionally cause severe allergic reactions: See leaflet for user warnings.

Wash hands after use.

10. EXPIRY DATE

Shelf life after first opening the immediate packaging: 28 days.

Discard unused material

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

POM-V

For animal treatment only. 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

Zoetis UK Limited

5th Floor, 6 St. Andrew Street

London

EC4A 3AE

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4044

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR: Duphamox LA 150 mg/ml Suspension for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Zoetis UK Limited

5th Floor, 6 St. Andrew Street

London

EC4A 3AE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphamox LA 150 mg/ml Suspension for Injection

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

Duphamox LA is a stable, injectable, off-white suspension containing 150 mg amoxicillin per ml as Amoxicillin Trihydrate. Each ml also contains Butylated Hydroxyanisole 0.08 mg as antioxidants.

4. INDICATION(S)

Duphamox LA is indicated in the treatment and control of infections caused by organisms sensitive to amoxicillin. 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 pneumonia*, *Proteus mirabilis*, *Salmonella* species, Straphylococci and Streptococci (non-penicillinase producing).

Duphamox LA 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 infections (treat before surgery)

5. CONTRAINDICATIONS

Not effective against beta-lactamase producing organisms

Do not use in known cases of hypersensitivity to penicillin or cephalosporins.

Not suitable for intravenous or intrathecal administration.

Not to be used in small herbivores such as rabbits, guinea pigs, gerbils and hamsters.

Not effective against penicillinase-producing organisms.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Cattle, sheep, pigs, dogs and cats

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

Shake well before use. Cattle, sheep and pigs: By intramuscular injection only.

Dogs and cats: by subcutaneous or intramuscular injection.

Massage the site after injection.

The recommended dosage rate is 15 mg per kg bodyweight equivalent to 1 ml per 10 kg bodyweight (repeat if necessary after 48 hours).

The suggested dosage rates are

Cattle 450 kg	45.0 ml
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Sheep 65 kg	6.5 ml
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Pigs 150 kg	15.0 ml
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Dogs 20 kg	2.0 ml
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Cats 5 kg	0.5 ml
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9. ADVICE ON CORRECT ADMINISTRATION

Swab the septum before removing each dose.

Use a dry, sterile needle and syringe.

If dose volume exceeds 20 ml, the dose should be divided and injected into 2 sites. Normal aseptic precautions should be observed. Use a dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin.

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: 23 days.

Cattle - milk: 84 hours.

Sheep and pigs - meat and offal: 16 days.

Not for use in sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

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

This product does not contain an antimicrobial preservative. Shelf life after first opening the immediate packaging: 28 days. Discard unused material.

When the container is broached/opened 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 determined. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

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 breathing, are more serious symptoms and required urgent medical attention.

Wash hands after use

For animal treatment only

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

May 2014

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription

Vm 42058/4044

FURTHER INFORMATION

Multidose vials of 50, 100, 250 and 500 ml. Not all pack sizes may be marketed.

After the administration of Duphamox LA, amoxicillin is absorbed and widely distributed in the body and high levels are found in kidney, urine, liver and bile. Amoxicillin has a rapid bactericidal action which normally prevents the recrudescence of respiratory infections. As with other penicillins, absence of toxicity is normally encountered. Animals with functional rumens should only be treated parenterally.

Approved: 18/01/2018

