PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphamox® 150 mg/ml Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains Amoxicillin 150 mg as Amoxicillin Trihydrate. Also contains Butylhydroxytoluene 0.08 mg and Butylhydroxyanisole 0.08 mg as antioxidant.

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, sheep, pigs, dogs & cats.

6. INDICATIONS

For the treatment of infections caused by or associated with organisms sensitive to amoxicillin.

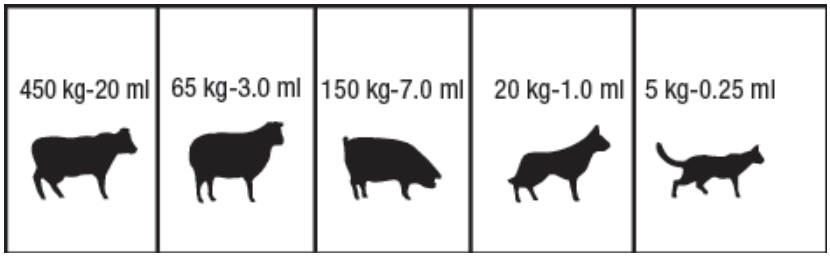
For use: See leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

SHAKE BEFORE USE.

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

Dosage: 7 mg/kg (equivalent to 1 ml per 20 kg) once daily for up to 5 consecutive days.



8. WITHDRAWAL PERIOD

Cattle

Meat and offal: 18 days

Milk: 24 hours

Sheep

Meat and offal: 10 days

Not for use in sheep producing milk for human consumption.

Pigs

Meat and offal: 16 days.

9. SPECIAL WARNING(S), IF NECESSARY

This product does not contain an antimicrobial preservative. Use a dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin. Massage the site after injection.

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.

User warning: Penicillins/cephalosporins may occasionally cause severe allergic reactions: See package leaflet for full user warnings.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

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

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

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4043

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:

Duphamox® 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
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Batch release site not currently stated

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphamox® 150 mg/ml Suspension for Injection

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

Duphamox is a stable, off-white suspension for injection containing 150 mg of amoxicillin (as Amoxicillin Trihydrate) per ml. Each ml also contains Butylhydroxytoluene 0.08 mg and Butylhydroxyanisole 0.08 mg as antioxidants.

4. INDICATIONS

Duphamox 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. *In vitro* it is effective against a wide range of Gram-positive and Gram-negative bacteria which include:

Actinomyces bovis, *Actinobacillus equuli*, *Actinobacillus lignieresi*, *Bacillus anthracis*, *Bordetella bronchiseptica*, *Clostridium* spp, *Corynebacterium* spp, *Erysipelothrix rhusiopathiae, Escherichia coli*, *Fusiformis* spp, *Haemophilus* spp, *Moraxella* spp, *Pasteurella* spp, *Proteus mirabilis*, *Salmonella* spp, Staphylococci and Streptococci (non-penicillinase producing) in cattle, sheep, pigs, dogs and cats.

5. CONTRAINDICATIONS

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.

Penicillins and cephalosporins may cause hypersensitivity (allergy, allergic skin reactions) after use. Allergic reactions may occasionally be serious (anaphylaxis).

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).

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 7 mg per kg bodyweight once daily for up to 5 days (equivalent to 0.25 ml per 5 kg daily).

The suggested dosage rates are

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

9. ADVICE ON CORRECT ADMINISTRATION

Normal aseptic precautions should be observed. Use a dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin.

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

A separate site should be used for each administration.

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: 18 days

Milk: 24 hours

Sheep

Meat and offal: 10 days

Not for use in sheep producing milk for human consumption.

Pigs

Meat and offal: 16 days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25ºC. Protect from light. Shake well before use.

This product does not contain an antimicrobial preservative.

Swab the septum before removing each dose.

Use a dry, sterile needle and syringe.

Keep out of the reach and sight of children.

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

12. SPECIAL WARNING(S)

Special warnings for each target species:

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

Complete cross-resistance has been shown between amoxicillin and other penicillins, in particular amino-penicillins.

Use of the product/amoxicillin should be carefully considered when antimicrobial susceptibility testing has shown resistance to penicillins because its effectiveness may be reduced.

User warnings:

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 require urgent medical attention.

Wash hands after use.

For animal treatment only

Interaction with other medicinal products and other forms of interaction:

It is not generally recommended to use bactericidal and bacteriostatic antibiotics at the same time.

Beta-lactam antibiotics are known to interact with antibiotics with bacteriostatic action such as chloramphenicol, macrolides, sulphonamides and tetracyclines.

There is also synergic action of penicillins with aminoglycosides.

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

April 2022

15. OTHER INFORMATION

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

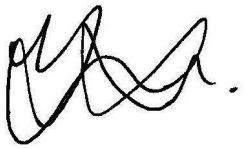
After the administration of Duphamox, amoxicillin is absorbed and widely distributed in the body and high levels are found in kidney, urine, liver and bile. Amoxicillin has a rapid bactericidal action which normally prevents the recrudescence of respiratory infections.

As with other penicillins, absence of toxicity is normally encountered. Animals with functional rumens should only be treated parenterally.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4043



Approved: 08 April 2022