SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphamox 150 mg/ml Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Each ml contains:
Amoxicillin Trihydrate equivalent to 150mg Amoxicillin

Excipient(s):
Butylhydroxytoluene 0.08 mg
Butylhydroxyanisole 0.08 mg
as antioxidants.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
An off white oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
Sheep
Pigs
Dogs
Cats

4.2 Indications for use, specifying the target species

For the treatment of infections caused by susceptible Gram-positive and Gram-negative organisms including:
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 mirablis
Salmonella spp
Staphylococci (non-penicillinase producing)
Streptococci (non-penicillinase producing)

4.3 Contraindications

Not suitable for intravenous or intrathecal use.
Do not use in small herbivores such as rabbits, hamsters, gerbils and guinea pigs.
Do not use in cases of known hypersensitivity.

4.4 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.

4.5 Special precautions for use

i) Special precautions for use in animals

Shake the container before use.
Swab the septum before removing each dose.
Use a dry, sterile needle and syringe.
This product does not contain an antimicrobial preservative.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

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 hands after use.

4.6 Adverse reactions (frequency and seriousness)

Occasional local tissue reaction may result from 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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 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, sulfonamides and tetracyclines. There is also synergic action of penicillins with aminoglycosides.

4.9 Amounts to be administered and administration route

Administration is by the intramuscular route for cattle, sheep and pigs and by the intramuscular or subcutaneous route in dogs and cats.
The dosage rate is 7mg/kg bodyweight daily for up to 5 days (equivalent to 0.25ml per 5kg daily). Massage the injection site after injection.

Animal	Weight (kg)	Dose volume (ml)
Cattle	450	20.0
Sheep	65	3.0
Pigs	150	7.0
Dogs	20	1.0
Cats	5	0.25

Normal aseptic precautions should be observed. A separate injection site should be used for each administration.

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

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable

4.11 Withdrawal periods

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

5. PHARMACOLOGICAL PROPERTIES

Amoxicillin is a broad-spectrum semi-synthetic penicillin bactericidal in action.

Amoxicillin predominately inhibits cell wall synthesis in susceptible bacteria. Amoxicillin has a unique mode of action which directly and irreversibly disrupts existing cell wall peptidoglycan rather than newly forming peptidoglycan of the divisory septal wall as with other members of the penicillin family.

After the administration of the product, Amoxicillin is widely absorbed and widely distributed in the body and high levels are found in kidney, urine, liver and bile.

ATC Vet Code: QJ01CA04

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole
Butylhydroxytoluene
Aluminium Stearate
Propylene Glycol Dicaprylocaprate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 12 months.
Shelf-life after opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
Following withdrawal of the first dose, use the product within 28 days.

6.5 Nature and composition of immediate packaging

50 ml and 100 ml clear, colourless Type III or Type II glass vials, closed with nitrile rubber bungs and aluminium overseals, and 50 ml and 100 ml clear plastic vials closed with nitrile rubber bungs and aluminium overseals.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

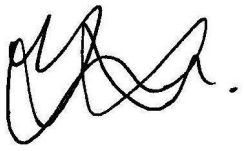
Vm 42058/4043

9. DATE OF FIRST AUTHORISATION

29 August 1986

10. DATE OF REVISION OF THE TEXT

April 2022



Approved: 08 April 2022