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

Not effective against beta-lactamase producing organisms.

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.

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

None known.

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

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 last treatment.
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.

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 Duphamox, 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 2021

Approved 14 April 2021