Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphamox 150 mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:		
Active Substance		
Amoxicillin Trihydrate	150	mg
Excipients		
Butylated hydroxytoluene (E321)	0.08	mg
Butylated hydroxyanisole (E320)	0.08	mg
(as antioxidants)		

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.
An off-white 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 a wide range of Gram-positive and Gram-negative pathogenic bacteria including:

Bacillus anthracis	*Haemophilus* spp.
Bacillus cereus	*Pasteurella* spp.
Bordetella bronchiseptica	*Proteus mirabilis*
Clostridium spp.	*Salmonella* spp.
Corynebacterium spp.	non-penicillinase producing
Erysipelothrix rhusiopathiae	Staphylococci
Escherichia coli	non-penicillinase producing
Fusiformis spp.	Streptococci

4.3 Contraindications

Do not use for intravenous or intrathecal use.
Do not use in rabbits, hamsters, gerbils and guinea pigs.
Do not use in sheep producing milk for human consumption.
Do not use in known cases of hypersensitivity to amoxicillin.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction 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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Occasional local tissue reaction may result from use of this product.
On rare occasions anaphylactic reactions may occur following use of this product.

4.7 Use during pregnancy, lactation or lay

Duphamox can be safely administered to pregnant and lactating animals. When used in lactating cows, observe the necessary withdrawal period.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

Administration is by the intramuscular or subcutaneous route.
The dosage rate is 7 mg/kg daily for up to 5 days in all species.
Shake bottle before use. Massage the injection site.

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

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

Normal aseptic precautions should be observed.

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

Not applicable.

4.11 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 48 hours from the last treatment.
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 7 days from the last treatment. Pigs may be slaughtered for human consumption only after 14 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterials for systemic use, Amoxicillin.
ATCvet Code: QJ01CA04.

5.1 Pharmacodynamic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated hydroxytoluene (E321)
Butylated hydroxyanisole (E320)
Aluminium stearate
Fractionated coconut oil

6.2 Incompatibilities

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The veterinary medicinal product is supplied in 100 ml Type II glass vials with a rubber nitrile bung and aluminium overseal.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/036/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13th February 2009

10 DATE OF REVISION OF THE TEXT

April 2012
August 2013