Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphamox LA 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

In vitro amoxicillin is effective against a wide range of Gram-positive and Gram-negative bacteria which include.

Bacillus anthracis, Bacillus cereus, Bordetella bronchiseptica, Clostridium spp., Corynebacterium spp., Erysipelothrix rhusiopathiae, Fusiformis spp., Haemophilus spp., Pasteurella spp., Proteus mirabilis, some Salmonella spp., Staphylococci (non penicillinase producing), *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 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 infection (treat before surgery).

4.3 Contraindications

This product is not suitable for intravenous or intrathecal use. Amoxicillin, like other Penicillins, should not be administered orally or parenterally in rabbits, hamsters, gerbils or guinea pigs. Duphamox LA should not be given to penicillin sensitive animals.

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 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 occur with use of Duphamox L.A.
On rare occasions anaphylactic or hypersensitivity-type reactions have been recorded following administration of the product.

4.7 Use during pregnancy, lactation or lay

Duphamox LA can be safely administered during pregnancy and lactation. When used in lactating cows, the necessary withdrawal period should be observed.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

Administer by subcutaneous or intramuscular injection.
The recommended dosage rate is 15 mg per kg bodyweight, repeatable if necessary after 48 hours. Shake well before use. Massage the injection site.

Animal	Weight (kg)	Dosage volume (ml)
Cattle	450 kg	45.0 ml
Sheep	65 kg	6.5 ml
Pigs	150 kg	15.0 ml
Dogs	20 kg	2.0 ml
Cats	5 kg	0.5 ml

Dose volume is equivalent to 1 ml per 10 kg bodyweight. If dose volume exceeds 20 ml, it should be divided and injected into two sites. As with other injectable preparations normal aseptic precautions should be observed (use dry syringes for extraction of suspension to avoid hydrolysis of amoxicillin).

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. Not for use in sheep producing milk for human consumption. Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 21 days from the last treatment. Sheep and 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

100 ml clear Type II multidose glass vials.
Closures: Butyl rubber nitryl bung with 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 10438/037/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20 February 2009

10 DATE OF REVISION OF THE TEXT

April 2012
August 2013