IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10861/018/001**
Case No: 7001703

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Fort Dodge Animal Health

Flanders Road, **Hedge End**, **Southampton SO30 4QH**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Duphamox LA 50ml

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphamox LA, 50ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Amoxicillin Trihydrate 150 mg

Excipients

Butylated hydroxytoluene 0.08 mg
Butylated hydroxyanisole 0.08 mg
(as antioxidants).

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

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 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 occur with use of Duphamox L.A.

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

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
Butylated Hydroxyanisole
Aluminium stearate
Fractionated Coconut Oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

Unopened : 2 years
In –use: Once a vial has been broached the contents should be used within 28 days.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

50 ml clear Type II multidose glass vials containing an off white sterile suspension.
Closures: Butyl rubber nitrile 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

Fort Dodge Animal Health Limited,
Flanders Road,
Hedge End,
Southampton,
SO30 4QH,
England.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10861/18/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17th May 2002