IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10995/020/001**
Case No: 7007546

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Ceva Animal Health Limited

90 The Broadway, **Chesham**, **Bucks HP15 1EG**, **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:

Aphatrim Solution for Injection, Micromol

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.

The authorisation, unless previously revoked, shall continue in force from until .

Signed on behalf of the Irish Medicines Board

_____

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Aphatrim Injectable Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance(s)	
Trimethoprim	40 mg
Sulfamethoxazole	200 mg
Excipient(s)	
Benzyl Alcohol	9.0 mg

3 PHARMACEUTICAL FORM

Solution for injection.

A clear, slighty pale yellow, viscous solution

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs and dogs.

4.2 Indications for use, specifying the target species

For the treatment of systemic infections caused by or associated with organisms sensitive to trimethorpim sulphamethoxazol combination. The spectrum of activity includes both gram positive and gram negative organisms including:

Actinobacilli,
Bordetella spp
Corynebacteria
Escherichia coli
Haemophilus spp
Klebsiella spp.
Pasteurella spp
Salmonella spp.
Staphylococci
Streptococci.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient(s).
Do not use in animals with severe liver parenchymal damage, or blood dyscrasias.
Do not use in animals exhibiting drug inducted cardiac arrhythmias, such arrhythmias may be associated with the administration of certain anesthetic and sedative agents.

4.4 Special warnings for each target species

Please see SPC in finalsch

4.5 Special precautions for use

Please see SPC in finalsch

4.6 Adverse reactions (frequency and seriousness)

- Intramuscular injection may be accompanied with (temporary)local irritation at the injection site.
- Hypersensitivity and cross-hypersensitivity reactions due to sulphonamides and/or Trimethoprim.
- Anaphylactic shock, potentially fatal, has been observed on rare occasions following administration of Potentiated Sulphonamide preparations, particularly by the intravenous route. Veterinary surgeons should be mindful of this possibility during the injection process. For intravenous administration, the product should be warmed to body temperature and administered over as long a period as is reasonably practical. At the first sign of intolerance, the injection should be interrupted. Intravenous administration should be used with extreme caution and only if therapeutically justified.

4.7 Use during pregnancy, lactation or lay

No objection if given in normal therapeutic doses.

4.8 Interaction with other medicinal products and other forms of interaction

Local anesthetics of the para-amninobenzoic group (like procaine, tetracaine) may abolish the local action of this product.

4.9 Amounts to be administered and administration route

For intramuscular or (slow) intravenous injection (cattle only).
The general recommended dose is 1 ml per 15 kg bodyweight (=2.6 mg Trimethoprim + 13.33 mg Sulphamethoxa-zole per kg) divided in 2 doses until 2 days after disappearance of the infectious symptoms for a maximum of 5 consecutive days.
Large volumes (> 20ml) should be injected at two different injection sites.

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

Not applicable

4.11 Withdrawal Period(s)

Edible tissues: 10 days
Milk: 3 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Antimicrobial. Aphatrim is a Trimethoprim/Sulphonamide combination of choice for the treatment of respiratory and gastro-intestinal infections.
The combination of Trimethoprim and Sulphamethoxazole has a potentiating antibacterial effect. The synergistic effect is strongly determined by the half life of the Sulphonamide. In comparison with Trimethoprim, the half life of Sulphamethoxazole turns out to be optimal.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Glycerol
N. N-Dimethylacetamide
Sodium Hydroxide

Water for Injections

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf-life of the vterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 30 days.

6.4 Special precautions for storage

Store below 25°C.
Do not freeze.
Protect from light

6.5 Nature and composition of immediate packaging

Supplied in amber glass bottles, 100 ml type II.
The bottles are closed with butyl/rubber stoppers and aluminium caps.

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

Ceva Animal Health,
90 The Broadway,
Chesham,
Bucks,
HP5 1EG,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10995/020/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 1998

10 DATE OF REVISION OF THE TEXT

29th October 2004