

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10995/023/001**
Case No: 7006814

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:

Trimazol 24% Solution for Injection

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 **03/06/2009**.

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

Trimazol 24% Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances

Sulfafurazole	200.0 mg
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Trimethoprim	40.0 mg
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Excipients

Benzyl Alcohol	10.0 mg
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For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs and sheep.

4.2 Indications for use, specifying the target species

Infections due to micro-organisms susceptible to sulfafurazole and trimethoprim including infections of the respiratory tract, urogenital tract, alimentary tract, as well as general infections.

4.3 Contraindications

Do not use in animals with known hypersensitivity to sulfonamides and trimethoprim.

4.4 Special warnings for each target species

Intravenous injections should be administered slowly.

4.5 Special precautions for use

Special precaution(s) for use in animals

Intravenous injections should be administered slowly over a period of not less than 30 seconds.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

Transient, very mild local tissue irritation may be occasionally observed following intramuscular administration.

4.7 Use during pregnancy, lactation or lay

Can be used.

4.8 Interaction with other medicinal products and other forms of interaction

Increases the anticoagulant effect of warfarin.

4.9 Amounts to be administered and administration route

Recommended daily dosage, IV or IM:

16 mg activity per kg b.w. (1 ml per 15 kg b.w.).

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

Administration of a double recommended dose IM once daily during three consecutive days caused no systemic reactions, and only very mild local tissue irritation was observed in some piglets (20-28 kg b.w.).

4.11 Withdrawal Period(s)

After IM treatment:

Cattle:

Edible tissues from slaughtered animal: 8 days.

Milk: 48 hours.

Pigs:

Edible tissues from slaughtered animal: 7 days.

Milk: Not applicable.

Sheep:

Edible tissues from slaughtered animal: 4 days.

Milk: Not for use in sheep producing milk for human consumption.

After IV treatment:

Cattle:

Edible tissues from slaughtered animal: 6 days.

Milk: 48 hours.

Pigs:

Edible tissues from slaughtered animal: 6 days.

Milk: Not applicable.

Sheep:

Edible tissues from slaughtered animal: 4 days.

Milk: Not for use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Therapeutical classification

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Pharmacological properties

Sulfafurazole and trimethoprim act synergistically to block the synthesis of bacterial folates at two separate stages. Folates are essential to the bacterial cell for multiplication and survival. These blocking agents kill a wide range of Gram-negative and Gram-positive bacteria and also reduce the possibility of bacterial resistance. Intramuscular injections with Trimazol-24 are very well tolerated causing negligible pain and very mild transient tissue irritations.

Effective therapeutic serum levels are produced within half an hour after injection.

One daily IM administration during 3 consecutive days was sufficient in treatment of respiratory tract infections in controlled clinical trials in calves, pigs and sheep.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Lactic Acid
Propylene Glycol
Formaldehyde solution
Diethanolamine
Water for Injection

6.2 Incompatibilities

Should not be mixed with other drugs.

6.3 Shelf-life

Two years if the vial has not been opened.

28 days after perforation of the stopper.

6.4 Special precautions for storage

Store at 2-8°C
Protect from light

6.5 Nature and composition of immediate packaging

Amber glass 100ml vial, Type I, with bromobutyl 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
Great Britain

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10995/023/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

3rd June 2009

10 DATE OF REVISION OF THE TEXT