IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10823/005/001**
Case No: 7004455

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:

Chem-Pharm

Ballyvaughan, **Co. Clare**, **Ireland**

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:

Intertrim 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 **30/09/2008**.

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

Intertrim Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substances	
Trimethoprim	40 mg
Sulfadiazine	200 mg
Excipients	
Chlorocresol	1 mg
Sodium Formaldehyde Sulfoxylate	1 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, yellow aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, cattle, pigs, cats and dogs.

4.2 Indications for use, specifying the target species

Intertrim Injection is indicated in the treatment of systemic infections caused by or associated with organisms sensitive to the Trimethoprim : Sulphadiazine combination. The spectrum of activity includes both Gram positive and Gram negative organisms including:

Actinobacilli	*Klebsiella* spp.
Bordetella spp.	*Pasteurella* spp.
Corynebacteria	*Salmonella* spp.
Eschericia coli	*Staphylococci*
Haemophilus spp.	*Streptococci*

4.3 Contraindications

Intertrim Injection should not be administered intraperitioneally.
Do not administer to animals known to be hypersensitive to the active ingredients
Do not administer to animals with known sulphonamide sensitivity or severe liver or kidney parenchymal damage or blood dyscrasias.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Adequate drinking water should be available during the therapeutic effect of the product. Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur the product should be discarded.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

To ensure a correct dosage bodyweight should be determined as accurately as possible.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

Anaphylactic shock, potentially fatal, has been observed on rare occasions following administration of potentiated sulphonamide preparations, particularly after 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.

Local reaction characterised by swelling and/or hardness may be observed at the injection site following treatment. These lesions are of a transient nature, resolving within one week after treatment.

4.7 Use during pregnancy, lactation or lay

Intertrim Injection can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer to horses exhibiting drug-induced cardiac arrhythmias. Such arrhythmias may be associated with the administration of certain anaesthetic and sedative agents.

4.9 Amounts to be administered and administration route

Cattle and Pigs
The recommended dose rate is 15 mg of active ingredients per kilogram bodyweight (1 ml per 16 kg bodyweight).

Administration is by intramuscular or slow intravenous injection only.

Maximum recommended volume to be administered at a single intramuscular site: 15 ml of product.

Horses:
The recommended dose rate is 15 mg of active ingredients per kilogram bodyweight (1 ml per 16kg bodyweight).

Administration is by slow intravenous injection only.

Dogs and Cats;
The recommened dose rate is 30 mg of active ingredients per kilogram bodyweight (1ml per 8kg bodyweight).

Administration is by subcutaneous injection only.

A single injection may be sufficient in uncomplicated cases, but in severe infections, treatment should be given until two days after the clinical signs have resolved, up to a maximum of five days.

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

Not applicable.

4.11 Withdrawal Period(s)

Edible tissues from slaughtered animal:

Cattle:	12 days from last treatment.
Pigs:	20 days from last treatment.
Horses:	28 days from last treatment.
Milk:	48 hours from last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01 EW10
Pharmacotherapeutic Group: Sulfadiazine and trimethoprim

5.1 Pharmacodynamic properties

Sulphadiazine (SDZ) inhibits the incorporation of para-aminobenzoic acid into folic acid and trimethoprim (TMP) inhibits the enzyme dihydrofolate reductase (DHFR) which converts dihydrofolic acid into tetrahydrofolic acid. TMP and SDZ act together synergistically with a double-blockade mode of action. The combination is bactericidal inhibiting sequential steps in the synthesis of purines which are required for DNA synthesis. TMP/SDZ combinations have a broad bactericidal action against many gram-positive and gram-negative aerobic bacteria, a large proportion of anaerobic bacteria, chlamydia and protozoa.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium formaldehyde sulfoxylate
Disodium edetate
Chlorocresol
N-Methyl pyrrolidone
Sodium hydroxide
Water for injections

6.2 Incompatibilities

None known

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

Store below 25ºC.
Do not freeze.
Protect from light.
Crystallisation of the product, which can occur at low temperatures, can be reversed by gentle warming.

6.5 Nature and composition of immediate packaging

The product is presented in 100 ml amber Type II glass vials sealed with nitryl rubber bungs.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chem-Pharm Ltd.,
Ballyvaughan,
Co. Clare.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/005/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT