Revised: February 2010
AN: 02037/2008

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Tyluvet 20% w/v, Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances	per ml	% w/v
Tylosin	200 mg	20
Excipients		
Benzyl Alcohol	41.66 mg	4.166

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection

A clear, sterile, yellow solution.

4. CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the target species

For the treatment in pigs of diseases involving organisms sensitive to tylosin, such as swine erysipelas (*Erysipelothrix rhusiopathiae*), and pneumonia (*Mycoplasma hyopneumoniae*)

4.3 Contraindications

Not to be used in animals known to be hypersensitive to the active ingredient.

4.4 Special Warnings for each Target Species

Not applicable

4.5 Special Precautions For Use

i. Special precautions for use in animals

Not recommended for horses.

Use of the product deviating from the instruction given in the SPC may increase the prevalence of bacteria resistant to tylosin and may decrease the effectiveness of treatment with other macrolide antimicrobials, due to potential for cross resistance.

Official, national and regional antimicrobial policies should be taken into account when the product is used.

ii. Special precautions to be taken by the person administering the product

Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical attention immediately. In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean, running water. Wash hands after use. Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa. Allergic reactions to these substances may occasionally be serious and therefore direct contact should be avoided. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions

Tolerance studies and toxicity studies suggest that undesirable effects are unlikely. Occasionally swelling at the injection site may occur, but this effect is transient.

4.7 Use During Pregnancy and Lactation

Reports of adverse reproductive effects have not been noted. Use with care in pregnant animals.

4.8 Interaction with medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration routes

0.5 ml /10 kg bodyweight, equivalent to 10 mg of tylosin per kg bodyweight, by deep intramuscular injection every 12 hours, up to a maximum of 6 injections.
Do not inject more than 5 mls at a single injection site.
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

4.10 Overdose

Tolerance studies of up to 156% of the recommended dosage rate have been carried out with localised swelling at the injection site being the only adverse effect. The lowest recorded LD_{50} for tylosin from other acute toxicity studies was 400mg/kg bodyweight (40 times the recommended dosage rate) by intravenous injection in mice.

4.11 Withdrawal Periods

Pigs (meat & offal): 46 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Macrolide antibiotic
ATCvet code: QJ01FA90

Tyluvet 20 injection is an antibiotic preparation for parenteral administration to pigs. The active ingredient is Tylosin, each ml of Tyluvet 20% contains 200 mg of the active ingredient. Tylosin is a macrolide antibiotic which acts by interfering with bacterial protein synthesis. It has a spectrum of activity and mode of action similar to that of erythromycin, being usually bacteriostatic and largely active against Gram-positive aerobes like *Erysipelothrix.* Macrolides are well absorbed and often concentrate within cells and macrophages thereby targeting intracellular pathogens including *Mycoplasmas*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Benzyl alcohol
Propylene glycol
Hydrochloric acid, concentrated (for pH adjustement) or
Sodium Hydroxide 20% Solution (for pH adjustement)
Water for injections

6.2 Incompatibilities

None known

6.3 Shelf Life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days

6.4 Special Precautions for Storage

Do not store above 25^{o}C
Protect from light.
Following withdrawal of the first dose use the product within 28 days.
Discard unused material.

6.5 Nature and composition of Immediate Packaging

Multidose 100 ml amber Type II glass vials sealed with a bromobutyl rubber stopper and capped with an aluminium overseal

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

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

7. MARKETING AUTHORISATION HOLDER

Cross Vetpharm Group Ltd
Broomhill Road
Tallaght
Dublin 24

8. MARKETING AUTHORISATION NUMBER(S)

Vm 12597/4023

9. DATE OF FIRST AUTHORISATION

26 October 2004

10. DATE OF REVISION OF TEXT

February 2010