Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tylovet 20% w/v Solution for injection for cattle and pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution for injections contains:
Active substance:
Tylosin (as tylosin tartrate) 200 mg
Excipients:
Benzyl alcohol 40 mg

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and pigs.

4.2 Indications for use, specifying the target species

For the treatment of infections caused by microorganisms susceptible to tylosin. The spectrum of antimicrobial activity of tylosin includes: *Staphylococcus* spp.; *Streptococcus* spp.; *Corynebacterium* spp.: *Neisseria* spp.; *Flavobacterium* spp.; *Campylobacter* spp.; *Bacillus anthracis; Moraxella bovis; Clostridium* spp.; *Haemophilus* spp.; *Bordetella bronchiseptica; Spirochaetes*; *Bacteroides* spp.; *Mycoplasma* spp.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to any other macrolide antibiotics or to any of the excipients.
Do not use in new-born animals.
Do not use in equine species.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
This product contains benzyl alcohol which has been documented to cause adverse reactions in neonates. For this reason this product should not be used in very young animals.
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid skin contact with the solution.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Use only according to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Do not mix with other solutions, since this may cause precipitation of the active ingredients.

4.9 Amounts to be administered and administration route

For intramuscular administration.
The recommended dosage rate is 10 mg/kg body weight twice daily; i.e. 0.5 ml per 10 kg body weight.
Treatment should be carried out for 3 to 5 consecutive days. To ensure a correct dosage, the body weight should be determined as accurately as possible.

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

Overdose should be avoided using the most accurate body weight estimation.

4.11 Withdrawal Period(s)

Cattle: Meat and offal: 21 days; Milk: 96 hours.
Pigs: Meat and offal: 21 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, macrolides.
ATCvet code: QJ01FA90.

5.1 Pharmacodynamic properties

Tylosin produces misreading of the genetic code. The drug probably acts by interacting with more than one site on the 50S ribosomal subunit, or with more than one component of the protein synthesis machinery. Tylosin has a broad spectrum of activity. *In vivo* tylosin is bacteriostatic in action.

5.2 Pharmacokinetic properties

It is absorbed relatively rapidly after injection and is distributed throughout the whole body. Only low concentrations are measured in plasma. In several tissues and tissue fluids, concentrations are achieved that are much higher than those in plasma (including lung and udder). Tylosin is inactivated by hepatic metabolism.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Propylene Glycol
Water for Injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

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: 14 days.

6.4 Special precautions for storage

Store in a refrigerator ($2^{\circ}C$ - $8^{\circ}C$).
Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

100 ml amber coloured type II glass vial sealed with a butyl rubber stopper and an aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10989/008/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th september 2008

10 DATE OF REVISION OF THE TEXT

December 2016