**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Label Text**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tyluvet 20% w/v, Solution for Injection

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

**COMPOSITION**

Each ml contains:

| | | |
|---|---|---|
| Tylosin | 200mg | 20%w/v |
| Benzyl Alcohol | 41.66 mg | 4.166% |

as preservative.

## 3. PHARMACEUTICAL FORM

A clear yellow, sterile solution suitable for parenteral administration

## 4. PACKAGE SIZE

Vial of 100ml

## 5. TARGET SPECIES

Pigs

## 6. INDICATION(S)

**USER INFORMATION**

Avoid accidental self injection and any contact with skin and eyes. Wash off any splashes immediately with clear running water. Seek medical attention if irritation persists. Wash hands after use. Following withdrawal of the first dose, use the product within 28 days. Discard unused material. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority**.**

**INDICATIONS**

For the treatment in pigs of diseases involving organisms sensitive to tylosin, including swine erysipelas and mycoplasma pneumonia.
Official, national and regional antimicrobial policies should be taken into account when the product is used.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

**ADMINISTRATION**

0.5ml/10kg bodyweight by deep intramuscular injection every 12 hours, up to a maximum of 6 injections.
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under dosing.

## 8. WITHDRAWAL PERIOD

**WITHDRAWAL PERIOD**
Pigs 46 days.

## 9. SPECIAL WARNING(S), IF NECESSARY

**CONTRA-INDICATIONS AND WARNINGS**
Do not inject more than 5ml at a single injection site. Not to be used in animals known to be hypersensitive to the active ingredient.

Tylosin and other macrolides may occasionally cause severe allergic reactions.
See package leaflet for full user warnings.

## 10. EXPIRY DATE

Expiry Date:

Once broached, use by:

## 11. SPECIAL STORAGE CONDITIONS

DO NOT STORE ABOVE 25°C.
PROTECT FROM LIGHT.

## 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

**Disposal:** Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.
To be supplied only on veterinary prescription. POM- V

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Distributed by:
VÉTOQUINOL UK Limited,
Vétoquinol House,
Great Slade,
Buckingham Industrial Park,
Buckingham MK18 1PA

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 12597/4023

## 17. MANUFACTURER'S BATCH NUMBER

Batch No:

# PACKAGE LEAFLET

Tyluvet 20 %w/v Solution for Injection

## 1. 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

VPA Holder and Manufacturer: Bimeda Chemicals Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland

Manufacturers:
Cross Vetpharm Group Limited Broomhill Road, Tallaght, Dublin 24, Ireland
Bimeda MTC Animal Health, 420 Beaverdale Road, Ontario, N3C 2W4, Canada
Eurovet Animal Health BV, Handelsweg 25, 5531 AE BLADEL, Netherlands

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tyluvet 20 %w/v, Solution for injection

## 3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

| | |
|---|---|
| Tylosin Base | 200 mg/ml |
| Benzyl Alcohol | 41.66mg/ml |

## 4. INDICATIONS

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

## 5. CONTRAINDICATIONS

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

## 6. ADVERSE REACTIONS

None known. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Pigs.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF

**ADMINISTRATION**

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 under dosing.

## 9. ADVICE ON CORRECT ADMINISTRATION

None.

## 10. WITHDRAWAL PERIOD

Pigs (meat & offal): 46 days

## 11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Keep out of reach and sight of children.
Following withdrawal of the first dose use the product within 28 days.
Discard unused material.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided.

## 12. SPECIAL WARNINGS

**Special precautions for use in animals**

Not recommended for horses.
Official, national and regional antimicrobial policies should be taken into account when the product is used.
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.

**Use during pregnancy and lactation**

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

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

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. 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.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2009

## 15. OTHER INFORMATION

UK authorised veterinary medicinal product.

MA No. Vm 12597/4023

Legal Category : POM-V To be supplied only on veterinary prescription.

Package Quantities:
Multidose vials of 100 ml.

Distributed by:
VÉTOQUINOL UK Limited,
Vétoquinol House,
Great Slade,
Buckingham Industrial Park,
Buckingham MK18 1PA

FOR ANIMAL TREATMENT ONLY

**Approved: 22/06/2017**