

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**CARTON 50ML & 100ML**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Marbocyl 10% Solution for Injection

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Containing:

10% w/v of marbofloxacin as active ingredient and 0.1 % w/v monothioglycerol and 0.2 % w/v m-cresol as preservatives, and 0.01 % w/v disodium edetate as a chelating agent.

**3. PHARMACEUTICAL FORM**

Sterile aqueous solution

**4. PACKAGE SIZE**

50 ml

100 ml

**5. TARGET SPECIES**

Cattle and pigs

**6. INDICATION(S) IN CATTLE**

MARBOCYL 10% is indicated in the treatment of respiratory infections caused by susceptible strains of organisms. It is also indicated in the treatment of acute *E.coli* mastitis.

**IN PIGS**

MARBOCYL 10% is indicated in the treatment of Metritis Mastitis Agalactia syndrome caused by susceptible strains of organisms.

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

2 mg/kg (1 ml/50 kg) in a single daily injection.

CATTLE: I.M., S.C. or I.V. route for 3 to 5 days

PIGS: I.M. route for 3 days

To avoid excessive broaching of the septum, the use of a draw-off needle is recommended.

## 8. WITHDRAWAL PERIOD

Cattle: Meat 6 days  
Milk 36 hours Pigs: Meat 4 days

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

See pack leaflet.

People with known hypersensitivity to (fluoro)quinolones should avoid using this product.

In case of contact with skin or eyes, rinse with plenty of water.

Accidental self-injection can induce a slight irritation.

In case of accidental self-injection, seek medical advice and show the label to the doctor.

Wash hands after use.

Official and local antimicrobial policies should be taken into account when the product is used. Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials. Whenever possible, fluoroquinolones should only be used based on susceptibility testing. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

## 10. EXPIRY DATE

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Following withdrawal of the first dose, the product should be used within 28 days. Keep the container in the outer carton.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Manure and slurry containing marbofloxacin should not be spread on the same area of land in successive years.

## 13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

POM-V

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

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

Vetoquinol UK Limited  
Steadings Barn  
Pury Hill Business Park  
Nr Alderton  
Towcester  
Northamptonshire  
NN12 7LS

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 08007/4149

**17. MANUFACTURER'S BATCH NUMBER**

**PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING**  
**UNITS**  
**50 ml LABEL**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Marbocyl 10% Solution for Injection

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

50 ml of sterile aqueous solution containing 10 % w/v of marbofloxacin as active ingredient and 0.1 % w/v monothioglycerol and 0.2 % w/v m-cresol as preservatives and 0.01 % w/v disodium edetate as a chelating agent.

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

50 ml

**4. ROUTE(S) OF ADMINISTRATION**

**DOSAGE AND ADMINISTRATION:**

2 mg/kg (1 ml/50kg) in a single daily injection.

**CATTLE:** I.M., S.C. or I.V. route for 3 to 5 days

**PIGS:** I.M. route for 3 days

**5. WITHDRAWAL PERIOD**

Milk: 36 hours

Meat: Cattle 6 days, Pigs 4 days

**6. BATCH NUMBER**

Lot:

**7. EXPIRY DATE**

Exp:

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

**INDICATIONS - CONTRA-INDICATIONS, WARNINGS - ETC:**

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

FOR ANIMAL TREATMENT ONLY. TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN. DO NOT STORE ABOVE 25°C. PROTECT FROM LIGHT. KEEP THE CONTAINER IN THE OUTER CARTON

POM-V

**PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE**  
**100 ml LABEL**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Marbocyl 10% Solution for Injection

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Contains 10% w/v marbofloxacin, 0.1% w/v monothioglycerol, 0.2% w/v m-cresol and 0.01% w/v disodium edetate.

**3. PHARMACEUTICAL FORM**

Solution for Injection

**4. PACKAGE SIZE**

100 ml

**5. TARGET SPECIES**

Cattle  
Pigs

**6. INDICATION(S)**

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

2 mg/kg (1 ml/50kg)

Cattle I.M., S.C. or I.V. for 3 to 5 days.  
Pigs I.M. for 3 days.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Milk: 36 hours  
Meat: Cattle 6 days, Pigs 4 days

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

## 10. EXPIRY DATE

Exp:

Following withdrawal of the first dose, the product should be used within 28 days.  
Once broached, use by:

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## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light. Keep the container in the outer carton.

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

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE** [*Distribution category*]

<b>POM-V</b>
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To be supplied only on veterinary prescription.

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

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

Vetoquinol UK Limited  
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NN12 7LS

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4149

## 17. MANUFACTURER’S BATCH NUMBER

Lot:



## 5. CONTRAINDICATIONS

Do not use in cases of resistance to other fluoroquinolones (cross-resistance).  
Do not use in cases of hypersensitivity to the active substance, to any other quinolone or to any of the excipients.

## 6. ADVERSE REACTIONS

Intramuscular or subcutaneous injections are well tolerated although in very rare cases transitory inflammatory lesions without clinical impact can occur at the injection site.

The frequency of adverse reactions is defined using the following convention:

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

## 7. TARGET SPECIES

Cattle and pigs

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

### DOSAGE AND ADMINISTRATION

The recommended dosage is 2 mg/kg (1ml/50 kg) in a single daily injection.

#### **CATTLE:**

Intramuscular, subcutaneous or intravenous routes for 3 to 5 days

#### **PIGS:**

Intramuscular route for 3 days

## 9. ADVICE ON CORRECT ADMINISTRATION

To avoid excessive broaching of the septum, the use of a draw-off needle is recommended.

## 10. WITHDRAWAL PERIOD(S)

**Cattle:** Meat – 6 days, Milk – 36 hours

**Pigs:** Meat – 4 days

## 11. SPECIAL STORAGE PRECAUTIONS

DO NOT STORE ABOVE 25°C AND PROTECT FROM LIGHT

The discard date should be calculated at the time of first opening and written in the space provided on the label. Any product remaining in the vial should be discarded after 28 days.

Keep the container in the outer carton

## **12. SPECIAL WARNING(S)**

### **OPERATOR WARNINGS**

People with known hypersensitivity to fluoroquinolones should avoid using this product. In case of contact with skin or eyes, rinse with plenty of water.

Accidental self-injection can induce a slight irritation.

In case of accidental self-injection, seek medical advice and show the label to the doctor.

Wash hands after use.

### **FURTHER INFORMATION**

Marbofloxacin may be used in pregnant and lactating cows and sows. No severe side-effects are to be expected at doses up to 3 or 5 times the recommended dose in cattle and pigs respectively. In particular, no lesions of the articular joints are encountered. For Animal Treatment Only

Official and local antimicrobial policies should be taken into account when the product is used. Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials. Whenever possible, fluoroquinolones should only be used based on susceptibility testing. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

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

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

Manure and slurry containing marbofloxacin should not be spread on the same area of land in successive years.

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

September 2023

## **15. OTHER INFORMATION**

POM – V To be supplied only on veterinary prescription  
*Vm 08007/4149*

### **PHARMACOLOGICAL PROPERTIES**

### **PHARMACODYNAMIC PROPERTIES**

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase. It is effective against a wide range of Gram-positive bacteria (in particular *Staphylococci*, *Streptococci*) and Gram-negative bacteria (*Escherichia coli*, *Salmonella typhimurium*, *Citrobacter*

*freundii*, *Enterobacter cloacae*, *Serratia marcescens*, *Morganella morganii*, *Proteus spp*, *Klebsiella spp*, *Shigella spp*, *Pasteurella spp*, *Haemophilus spp*, *Moraxella spp*, *Pseudomonas spp*) as well as *Mycoplasma spp*.

### **PHARMACOKINETIC PROPERTIES**

After subcutaneous or intramuscular administration in cattle and intramuscular administration in pigs at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5 µg/ml within less than 1 hour. Its bioavailability is close to 100 %. It is weakly bound to plasma proteins (less than 10% in pigs and 30 % in cattle), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, uterus, digestive tract) it achieves higher concentrations than in plasma. In cattle, marbofloxacin is eliminated slowly in pre-ruminating calves ( $t_{1/2\beta} = 5-9$  h) but faster in ruminant cattle ( $t_{1/2\beta} = 4-7$  h) predominantly in the active form in urine (3/4 in pre-ruminating calves, 1/2 in ruminants) and faeces (1/4 in pre-ruminating calves, 1/2 in ruminants). In pigs, marbofloxacin is eliminated slowly ( $t_{1/2\beta} = 8-10$  h) predominantly in the active form in urine (2/3) and faeces (1/3).

Approved 21 September 2023

