

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON
MARBOCYL 2 % SOLUTION FOR INJECTION**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl 2% Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin

3. PHARMACEUTICAL FORM

Solution for injection

100 ml of sterile aqueous solution containing 2% w/v of marbofloxacin as active ingredient, 0.05% w/v 1-thioglycerol and 0.2 % w/v m-cresol as preservatives, and 0.01% w/v disodium edetate as a chelating agent.

4. PACKAGE SIZE

100 ML

5. TARGET SPECIES

Cattle and Pigs

6. INDICATION(S)

FOR USE IN PIGS AND PRE-RUMINATING CALVES UP TO 100 KG B.W.

MARBOCYL 2% is indicated in the treatment of respiratory infections caused by susceptible strains of organisms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

2 mg/kg (1 ml/10 kg) in a single daily injection.

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

PIGS: I.M. route for 3 to 5 days

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

8. WITHDRAWAL PERIOD

	CATTLE	PIGS
MEAT	6 days	4 days

9. SPECIAL WARNING(S), IF NECESSARY

(See package leaflet)

People with known hypersensitivity to fluoroquinolones should avoid using this product. Wash hands after use.

Following withdrawal of the first dose, the product should be used within 28 days. Manure and slurry containing marbofloxacin should not be spread on the same area of land in successive years.

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

For expiry date and lot number see bottom of carton.

11. SPECIAL STORAGE CONDITIONS

STORE BELOW 25°C.
PROTECT FROM LIGHT

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.

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

[Distribution category]

For animal treatment only

POM-V

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 SA
34 Rue de Chene Sainte-Anne
Magny-Vernois
70200 Lure
France

16. MARKETING AUTHORISATION NUMBER

Vm 06462/3024

17. MANUFACTURER’S BATCH NUMBER

Batch No.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – LABEL

MARBOCYL 2 % SOLUTION FOR INJECTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocyl 2% Solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin

3. PHARMACEUTICAL FORM

Solution for injection

COMPOSITION

100 ml of sterile aqueous solution containing 2 % w/v of marbofloxacin as active ingredient, 0.05 % w/v 1- thioglycerol and 0.2 % w/v m-cresol as preservatives, and 0.01% disodium edetate as a chelating agent.

4. PACKAGE SIZE

100 ML

5. TARGET SPECIES

Calves and Pigs

6. WITHDRAWAL PERIOD

Milk: N/A - Meat: Calves 6 days, Pigs 4 days

7. METHOD AND ROUTE OF ADMINISTRATION

2 mg/kg (1 ml/10 kg) in a single daily injection. pre ruminating calves up to 100 kg b.w. : I.V. route for 3 to 5 days or S.C. for 3 days.
pigs : I.M. for 3 to 5 days

8. SPECIAL WARNINGS, IF NECESSARY

See package leaflet

Following withdrawal of the first dose, the product should be used within 28 days
CATTLE (pre-ruminants up to 100 kg)

PIGS 100 ml containing 2 % w/v marbofloxacin , 0.05 % w/v 1- thioglycerol and 0.2 % w/v m-cresol as preservatives, and 0.01% disodium edetate

9. EXPIRY DATE

Exp:

10. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For use in pigs and pre-ruminants up to 100 kg b.w.

For animal treatment only.

Store below 25°C and protect from light.

Following withdrawal of the first dose, the product should be used within 28 days

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol SA
34 Rue de Chene Sainte-Anne
Magny-Vernois
70200 Lure
France

15. MARKETING AUTHORISATION NUMBER

Vm 06462/3024

16. MANUFACTURER’S BATCH NUMBER

Lot:

MARBOCYL 2 % SOLUTION FOR INJECTION – Package leaflet

**Antimicrobial
COMPOSITION**

100 ml of sterile aqueous solution containing 2 % w/v of marbofloxacin as active ingredient, 0.05 % w/v 1-thioglycerol and 0.2 % w/v m-cresol as preservatives, and 0.01% disodium edetate as a chelating agent.

MARBOCYL® 2%: VM 06462/3024

MARBOCYL 2 % is packaged in amber type II glass vials of 100 ml S.C and I.V. in pre-ruminant calves up to 100 kg b.w.; I.M. in pigs

Indications

FOR USE IN PIGS AND PRE RUMINATING CALVES UP TO 100 KG B.W.
MARBOCYL® 2% is indicated in the treatment of respiratory infections caused by susceptible strains of organisms.

Dosage and administration

The recommended dosage is 2 mg/kg (**1ml/10 kg**) in a single daily injection.

CATTLE:

Intravenous route for 3 to 5 days or subcutaneous route for 3 days.

PIGS:

Intramuscular route for 3 to 5 days

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

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*) and Gram negative bacteria (*Escherichia coli*, *Salmonella typhimurium*, *Campylobacter jejunii*, *Citrobacter freundii*, *Enterobacter*, *Proteus spp*, *Klebsiella spp*, *Actinobacillus pleuropneumoniae*, *Bordetella bronchiseptica*, *Pasteurella haemolytica*, *Pasteurella multocida*, *Haemophilus spp*, *Moraxella spp*, *Pseudomonas aeruginosa*) as well as Mycoplasma (*Mycoplasma bovis*, *Mycoplasma dispar*, *Mycoplasma hyopneumoniae*).

Pharmacokinetic properties:

After subcutaneous administration in cattle and intramuscular administration in pigs at the recommended dose of 2 mg/kg, **Marbofloxacin** is readily absorbed and 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) predominantly in the active form in urine (3/4) and faeces (1/4). 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).

Contra-indications

None

Undesirable effects (frequency and seriousness)

Subcutaneous injection is well tolerated. Transitory inflammatory reactions are sometimes observed at the injection site, but without clinical impact. The volume of injection should be limited to 10 ml at each site of injection for pigs. No severe side-effects are to be expected at doses up to 5 times the recommended dose in cattle and pigs. In particular no lesions of the articular joints are encountered. Overdosage may cause acute signs in the form of neurological disorders which would have to be treated symptomatically.

Withdrawal periods

	MEAT
CATTLE	6 days
PIGS	4 days

Operator warnings

People with known hypersensitivity to fluoroquinolones should avoid using this product. Wash hands after use.

Further information

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN STORE BELOW 25°C AND PROTECT FROM LIGHT

Following withdrawal of the first dose, use the product within 28 days. When the container is broached for the first time, using the in-use shelf-life above, any product remaining in the container should be discarded. The discard date (28 days after opening) should be written in the space provided on the label. Keep the container in the outer carton. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. To be supplied only on veterinary prescription. 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.

For animal treatment only

Distributed by:

Vetoquinol SA
34 Rue de Chene Sainte-Anne
Magny-Vernois
70200 Lure
France

License holder:

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Gavin Hall
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