LABEL 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

The UK, Ireland,	Marbocyl Solo 10% solution for injection for cattle
Spain	Marbocyl Bovinos 100 mg/ml solution for injection for cattle
Germany, Austria, The Netherlands, Belgium, Italy, Poland, Portugal, The Slovak Republic, The Czech Republic, Greece, Luxembourg, France	Marbocyl S 10% solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Marbofloxacin.....100.0 mg/ml

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use

5. WITHDRAWAL PERIOD

Meat and offal: 3 days
Milk : 72 hours

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp:
Shelf life after first opening the immediate packaging: 28 days
Once opened, use by

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

LABEL 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

The UK, Ireland,	Marbocyl Solo 10% solution for injection for cattle
Spain	Marbocyl Supra 100 mg/ml solution for injection for cattle
Germany, Austria, The Netherlands, Belgium, Italy, Poland, Portugal, The Slovak Republic, The Czech Republic, Greece, Luxembourg, France	Marbocyl S 10% solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin .....100.0 mg

Disodium edetate.....0.1 mg
Thioglycerol .....1.0 mg
metacresol .....2.0 mg

Excipient to .....1 ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml vial
250 ml vial

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 3 days
Milk: 72 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

Exp:
Shelf life after first opening the immediate packaging: 28 days
Once opened, use by

11. SPECIAL STORAGE CONDITIONS

Protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

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

Not requested on the immediate label.

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

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

Not requested on the immediate label.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Refer to Appendix 1

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

The UK, Ireland,	Marbocyl Solo 10% solution for injection for cattle
Spain	Marbocyl Bovinos 100 mg/ml solution for injection for cattle
Germany, Austria, The Netherlands, Belgium, Italy, Poland, Portugal, The Slovak Republic, The Czech Republic, Greece, Luxembourg, France	Marbocyl S 10% solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin .....100.0 mg

Disodium edetate.....0.1 mg
Thioglycerol .....1.0 mg
metacresol .....2.0 mg

Excipient to .....1 ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

Box containing one 50 ml vial
Box containing one 100 ml vial
Box containing one 250 ml vial

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 3 days
Milk : 72 hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Exp:
Shelf life after first opening the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

Protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

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

Any unused product or waste material should be disposed of in accordance with national requirements

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

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Refer to Appendix 1

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

LEAFLET

The UK, Ireland,	Marbocyl Solo 10% solution for injection for cattle
Spain	Marbocyl Bovinos 100 mg/ml solution for injection for cattle
Germany, Austria, The Netherlands, Belgium, Italy, Poland, Portugal, The Slovak Republic, The Czech Republic, Greece, Luxembourg, France	Marbocyl S 10% solution for injection

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

Please refer to Appendix 1

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

The UK, Ireland,	Marbocyl Solo 10% solution for injection for cattle
Spain	Marbocyl Bovinos 100 mg/ml solution for injection for cattle
Germany, Austria, The Netherlands, Belgium, Italy, Poland, Portugal, The Slovak Republic, The Czech Republic, Greece, Luxembourg, France	Marbocyl S 10% solution for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Marbofloxacin .....100.0 mg

Disodium edetate.....0.1 mg
Thioglycerol .....1.0 mg
metacresol .....2.0 mg

Excipient to .....1 ml

4. INDICATION(S)

Therapeutic treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Histophilus somni*.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to fluoroquinolones.
Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (cross resistance).

6. ADVERSE REACTION

Fluoroquinolones are known to induce arthropathies. Nevertheless, this effect has never been observed with marbofloxacin in cattle.
Administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which may persist for at least 12 days after injection. No other adverse effect was observed on cattle.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

The recommended dosage is 8 mg/kg body weight i.e. 2 ml /25kg body weight in a single intramuscular injection
If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.

9. ADVICE ON CORRECT ADMINISTRATION

Use of the product should be based on susceptibility testing and has to take into account official and local antimicrobial policies.
It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions that have responded poorly, or are expected to respond poorly, to other classes of antibiotics.

10. WITHDRAWAL PERIOD

Meat and offal: 3 days
Milk: 72 hours

11. SPECIAL STORAGE PRECAUTIONS

Protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.
Keep out of the reach and sight of children.
Shelf-life after first opening the immediate packaging: 28 days.
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 container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNINGS

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.

People with known hypersensitivity to quinolones should avoid any contact with the product.
If the product comes into contact with the skin or eyes, rinse with copious amounts of water.
Accidental self-injection can induce a slight irritation.

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, embryotoxic or maternotoxic effect associated with the use of marbofloxacin. Safety of the product at 8 mg/kg has not been determined in pregnant cows or in suckling calves when used in cows. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

No sign of overdosage has been observed after administration of 3 times the recommended dose. Overdosage may cause signs such as acute neurological disorders which should be treated symptomatically.

Do not mix with other medicinal products

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes: vial of 50, 100, 250 ml
Not all pack sizes may be marketed

APPENDIX 1

MARBOCYL S ®

Solution for injection
MRP n° FR/V/168/01/MR

MARKETING AUTHORISATION HOLDER

FR/PT/LU/IT/EL/PL	**VETOQUINOL S.A.** Magny-Vernois, BP 189 F-70204 LURE CEDEX (FRANCE)
AUSTRIA	**VETOQUINOL ÖSTERREICH GmbH** Zehetnergasse 24 A-1140 WIEN (AUSTRIA)
GERMANY	**VETOQUINOL GmbH** Parkstrasse 10 88212 RAVENSBURG (GERMANY)
BELGIUM	**VETOQUINOL S.A. - N.V.** Kontichsesteenweg 42 B-2630 AARSELAAR (BELGIUM)
THE NETHERLANDS	**VETOQUINOL B.V.** Postbus 3191, 5203 DD 'S-HERTOGENBOSCH (THE NETHERLANDS)
SK/CZ	**VETOQUINOL s.r.o.** Zamecnicka 411 28802 NYMBURK (CZECH REPUBLIC)
SPAIN	**VETOQUINOL ESPECIALIDADES VETERINARIAS** Parque Empresarial San Fernando, Edificio Italia 28830 SAN FERNANDO DE HENARES, MADRID (SPAIN)
UK/IE	**VETOQUINOL UK Ltd** Vetoquinol House Great Slade Buckingham Industrial Park Buckingham MK18 1PA (UNITED-KINGDOM)

MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

VETOQUINOL S.A.
Magny-Vernois, BP 189
F-70204 LURE CEDEX
FRANCE