

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE
BOX OF 50 ml / 100 ml / 250 ml**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl swine 160 mg/ml solution for injection for pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Marbofloxacin160 mg
Benzyl alcohol (E 1519)15 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

Vial of 50 ml
Vial of 100 ml
Vial of 250 ml

5. TARGET SPECIES

Pigs.

6. INDICATIONS

Not included.

7. METHOD AND ROUTES OF ADMINISTRATION

Intramuscular route.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 9 days.

9. SPECIAL WARNINGS

The sentence "Read the package leaflet before use" is already included under section 7.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Not applicable.

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

Disposal: read package leaflet.

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 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

Vm 08007/4134

Cardboard box with 1 vial of 50 ml:
Cardboard box with 1 vial of 100 ml:
Cardboard box with 1 vial of 250 ml:

17. MANUFACTURER’S BATCH NUMBER

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Label of 100 and 250 ml vials**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl swine 160 mg/ml solution for injection for pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Marbofloxacin160 mg/ml
Benzyl alcohol (E 1519)15 mg/ml

3. PHARMACEUTICAL FORM

Not requested.

4. PACKAGE SIZE

Vial of 100 ml
Vial of 250 ml

5. TARGET SPECIES

Pigs.

6. INDICATIONS

Not requested.

7. METHOD AND ROUTES OF ADMINISTRATION

1ml/20 kg
Single IM injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 9 days.

9. SPECIAL WARNINGS

The sentence "Read the package leaflet before use" is already included under section 7.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days.
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Not applicable.

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

Not requested.

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 SIGHT AND REACH OF CHILDREN”

Not requested on the immediate label.

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

Not requested on the immediate label.

17. MANUFACTURER’S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Labels of 50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl Swine 160 mg/ml solution for injection for pigs
Marbofloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE

Marbofloxacin 160 mg/ml

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

Vial of 50 ml.

4. ROUTES OF ADMINISTRATION

1ml/20 kg
Single IM injection.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Meat and offal: 9 days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days.
Once broached, use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PACKAGE LEAFLET

Forcyl Swine 160 ml/ml solution for injection for pigs

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

Marketing Authorisation Holder:

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

Manufacturer responsible for batch release:

Vetoquinol SA
Magny vernois
70200 Lure
FRANCE

Or

Vetoquinol Biowet Sp. z o.o.
ul. Kosynierów Gdyńskich 13-14
66-400 Gorzów Wielkopolski
POLAND

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forcyl Swine 160 mg/ml solution for injection for pigs
Marbofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One ml contains:

Marbofloxacin160 mg
Benzyl alcohol (E 1519).....15 mg

Clear yellow greenish to yellow brownish solution.

4. INDICATIONS

In fattening pigs: - Treatment of respiratory tract infections caused by susceptible strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*

In weaned piglets: - Treatment of intestinal infections caused by susceptible strains of *E. coli*

In post-partum sows:

- Treatment of metritis mastitis agalactia syndrome (form of postpartum dysgalactiae syndrome, PPDS) caused by susceptible strains of *E. coli*.

5. CONTRA-INDICATIONS

Do not use in animals with known hypersensitivity to fluoroquinolones or to any of the excipients.

To limit development of resistance, do not use fluoroquinolones as prophylaxis or metaphylaxis to prevent diarrhoea at weaning.

6. ADVERSE REACTIONS

Local reactions can be observed at the injection site, which disappear within 36 days. Pain at the injection site has been commonly reported (more than 1 but less than 10 animals in 100 animals).

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

7. TARGET SPECIES

Pigs (fattening pigs, weaned piglets, sows).

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

The recommended dosage is 8 mg/kg body weight i.e. 1 ml/20 kg body weight in a single intramuscular injection in the side of the pig neck.

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Meat and offal: 9 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Shelf-life after first opening the container: 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.

Do not use after the expiry date stated on the carton and vial after EXP.

12. SPECIAL WARNINGS

Special warnings for each target species

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

Special precautions for use in animals

Official and local antimicrobial policies should be taken into account when this 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. Wherever possible, use of the product should only be based on susceptibility testing.

Use of the product deviating from the instructions given in this 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.

User warnings

People with known hypersensitivity to (fluoro)quinolones and benzyl alcohol should avoid any contact with the product.

Wash hands after use. Avoid contact of the skin and eyes with the product. If the product comes into contact with the skin or eyes, rinse with copious amounts of water.

Care should be taken to avoid accidental self-injection. In the event of accidental self-administration, the user should immediately seek professional medical care.

Accidental self-injection can induce a slight irritation.

Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, embryotoxic or maternotoxic effect. The safety of the veterinary medicinal product at 8 mg/kg has not been established at 8 mg/kg in pregnant sows or in suckling piglets when used in sows. Use only according to the benefit/risk assessment carried out by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

None known.

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

Lesions of the joint cartilage, potentially leading to difficulties in movement, were observed in some animals treated at 24 mg/kg for three times the recommended dose and treatment duration.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Cardboard box with 1 vial of 50 ml:
Cardboard box with 1 vial of 100 ml:
Cardboard box with 1 vial of 250 ml:
Not all pack sizes may be marketed.

Approved: 11 September 2018

