# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FORCYL swine 160 mg/ml solution for injection for pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:
**Active substance (s):**
Marbofloxacin..... 160 mg

**Excipient (s):**
Benzyl alcohol (E 1519)…….... 15 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow greenish to yellow brownish solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Pigs (fattening pigs, weaned piglets, sows).

### 4.2 Indications for use, specifying the target species

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*.

### 4.3 Contraindications

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.

## 4.4 Special warnings <for each target species>

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

## 4.5 Special precautions for use

### 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.

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

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.

## 4.6 Adverse reactions (frequency and seriousness)

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).

## 4.7 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 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.

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

### 4.9 Amounts to be administered and administration route

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.

### 4.10 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 three times the recommended dose and treatment duration.

### 4.11 Withdrawal period(s)

Meat and offal: 9 days.

## 5. PHARMACOLOGICAL PROPERTIES

ATC Vet code: QJ01MA93
Pharmacotherapeutic group: antibacterials for systemic use

### 5.1 Pharmacodynamic properties

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group, which acts by inhibition of DNA gyrase. It has a broad-spectrum activity in vitro against Gram-positive bacteria and, Gram-negative bacteria.

Between 2009 and 2013, the activity of marbofloxacin against *Pasteurella multocida* (n=444) and *Escherichia coli* (n=1226) isolated from swine diseases in Europe was for *P. multocida:* MIC range*:* 0,004-1 µg/ml, $MIC_{50}$: 0.013µg/ml $MIC_{90}$: 0,028µg/ml and for *E. coli* (digestive infections): MIC range 0,008-64µg/ml; $MIC_{50}$:0,026µg/ml; $MIC_{90}$:0,681µg/ml, for E. coli (MMA syndrome): MIC range 0,015-16µg/ml; $MIC_{50}$:0,024µg/ml; $MIC_{90}$:0,475µg/ml. Marbofloxacin MIC distribution among E. coli strains isolated from digestive or MMA syndrome are similar with a trimodal distribution.

The clinical breakpoints defined for marbofloxacin are S ≤ 1 µg/mL, I = 2 µg/mL and R ≥ 4 µg/mL for Pasteurellaceae according to the “Comité de l’Antibiogramme de la Société Française de Microbiologie” (=French Society of Microbiology) (CA-SFM 2013).

Between 2009 and 2012, the activity of marbofloxacin against *Actinobacillus pleuropneumoniae* (n=157) isolated from swine diseases in Europe was: MIC range: 0.015-2µg/mL, $MIC_{50}$: 0.03µg/mL, $MIC_{90}$: 0.06µg/mL
The activity of marbofloxacin against the target bacterial species is bactericidal concentration-dependent.

A decrease of susceptibility of *Campylobacter spp*. against fluoroquinolones was observed since 1999.

Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding. To date, only sporadic cases have been reported for plasmid mediated fluoroquinolone resistance in animals. Depending on the underlying resistance mechanism cross-resistance to other (fluoro)quinolones and co-resistance to other antimicrobial classes can occur.

### 5.2 Pharmacokinetic particulars

After administration of an intramuscular dose of 8 mg/kg, the following mean plasmatic pharmacokinetic parameters were observed:

| Parameter | Fattening pigs | Weaned pigs | Sows |
|---|---|---|---|
| $T_{max}$ | 0.95 h | 0.93 h | 1 h |
| $C_{max}$ | 6.295 µg/mL | 5.550 µg/mL | 5.809 µg/mL |
| $AUC_{INF}$ | 114.7 µg.h/mL | 79.89 µg.h/mL | 112.0 µg.h/mL |
| T½lz | 15.14 h | 13.23 h | 11.92 h |
| F | 91.53 % | 89.57 % | nc |

$C_{max}$ = maximal plasmatic concentration;$T_{max}$ = mean observed occurrence time of the Cmax; $AUC_{INF}$ = area under the concentration-time curve extrapolated to infinity; T½lz = mean elimination half-life; F mean absolute bioavailability; nc: not calculated

Marbofloxacin is extensively distributed. Uterus tissue concentrations in sows reach Cmax of 9.346 µg/g in the uterine body observed at Tmax of 1.00 h after administration and the AUClast was 105.4 µg.h/g.
Binding to plasma proteins is weak, about 4%. In pigs, the elimination is predominantly as the active form in urine and faeces.

Marbofloxacin is eliminated slightly faster in post-weaning piglets than in heavier animals.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Benzyl alcohol (E1519)
Glucono-delta-lactone
Water for injections

### 6.2 Incompatibilities

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

### 6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days

## 6.4. Special precautions for storage

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

## 6.5 Nature and composition of immediate packaging

Details of the primary packaging:
Amber type II glass vials
Chlorobutyl rubber stopper
Aluminium cap or flip cap

Pack sizes:
Cardboard box containing one 50 ml vial
Cardboard box containing one 100 ml vial
Cardboard box containing one 250 ml vial

Not all pack sizes may be marketed.

## 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

## 7. MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER

Vm 08007/4134

## 9. DATE OF FIRST AUTHORISATION

22 August 2012

## 10. DATE OF REVISION OF THE TEXT

September 2018

Approved: 11 September 2018

D Austin