SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kelacyl 100 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Marbofloxacin 100 mg

Excipients:
Disodium edetate 0.10 mg
Monothioglycerol 1 mg
Metacresol 2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Yellow greenish to yellow brownish, clear solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and pigs (sows).

4.2 Indications for use, specifying the target species

In cattle:
- treatment of respiratory infections caused by strains of *Histophilus somni, Mannheimia haemolytica*, *Mycoplasma bovis*, *Pasteurella multocida* susceptible to marbofloxacin.
- treatment of acute mastitis caused by strains of *Escherichia coli* susceptible to marbofloxacin during the lactation period.

In pigs:
- treatment of Postpartum Dysgalactia Syndrome –PDS-(Metritis Mastitis Agalactia syndrome), caused by bacterial strains susceptible to marbofloxacin.

4.3 Contraindications

Do not use in cases where the pathogen involved is resistant 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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.

The efficacy data showed that the product has insufficient efficacy for the treatment of acute forms of mastitis induced by gram-positive bacteria.

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

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product. Care should be taken to avoid accidental self-injection as it can induce a slight irritation.
In case of accidental self injection, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of contact with skin or eyes, rinse with plenty of water.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Transitory inflammatory lesions can occur very rarely at the injection site, without clinical impact, when administered via the intramuscular or subcutaneous route.

Administration by the intramuscular route may cause very rarely 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.

However, in cattle, the subcutaneous route was shown to be better tolerated locally than the intramuscular route. Therefore, the subcutaneous route is recommended in heavy cattle.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

Safety of the veterinary medicinal product at 2 mg/kg body weight has been established in pregnant cows or in sucking calves and piglets when used in cows and sows. Can be used during pregnancy and lactation.

Safety of the veterinary medicinal product at 8 mg/kg body weight has not been established in pregnant cows or in sucking calves when used in cows. Therefore, this dose regimen should be used only according to the benefit/risk assessment by the responsible veterinarian.

In case of use in lactating cow, see section 4.11.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Route of administration:
Cattle: Intramuscular, subcutaneous or intravenous
Pigs: Intramuscular

Cattle:

Respiratory infections:
The recommended dosage is 8 mg marbofloxacin/kg body weight (2 ml veterinary medicinal product/25 kg body weight) in a single injection by the intramuscular route. If the volume to be injected is more than 20 ml, it should be divided between two or more injection sites.
In cases of respiratory infections caused by *Mycoplasma bovis*, the recommended dose is 2 mg marbofloxacin/kg body weight (1 ml veterinary medicinal product/50 kg body weight), in a single daily injection for 3 to 5 consecutive days, by the intramuscular or subcutaneous route. The first injection may be given by the intravenous route.

Acute mastitis:
Intramuscular or subcutaneous use:
The recommended dosage is 2 mg marbofloxacin/kg body weight (1 ml veterinary medicinal product/50 kg body weight) in a single daily injection, for 3 consecutive days. The first injection may also be given by the intravenous route.

Pigs (sows):

Intramuscular use:
The recommended dosage is 2 mg marbofloxacin/kg body weight (1 ml veterinary medicinal product/50 kg body weight) in a single daily injection, for 3 consecutive days.

To ensure administration of a correct dose, body weight should be determined as accurately as possible, to avoid underdosing.
In cattle and pig, the preferred injection site is the neck area.
The cap may be safely punctured up to 30 times. The user should choose the most appropriate vial size according to the target species to treat.

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

No signs of overdosage have been observed after administration of 3 times the recommended dose.
Signs such as acute neurological disorders may occur when the dose is exceeded. This signs should be treated symptomatically. Do not exceed the recommended dose.

4.11 Withdrawal period(s)

Cattle:

Indication	**Respiratory**		**Mastitis**
Dosage	2 mg/kg for 3 to 5 days (IV/IM/SC)	8 mg/kg on a single occasion (IM)	2 mg/kg for 3 days (IV/IM/SC)
Meat and offal	6 days	3 days	6 days
Milk	36 hours	72 hours	36 hours

Pigs:
Meat and offal: 4 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Fluoroquinolones,
ATCvet code: QJ01MA93

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-negative bacteria (*E. coli*, *Histophilus somni*, *Mannheimia haemolytica* and *Pasteurella multocida*) and against Mycoplasma (*Mycoplasma bovis*). Resistance to *Streptococcus* may occur.

Strains with MIC ≤ 1 µg/ml are susceptible to marbofloxacin whereas strains with MIC ≥ 4 µg/ml are resistant to marbofloxacin.

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.

5.2 Pharmacokinetic particulars

After subcutaneous or intramuscular administration in cattle and intramuscular administration in pigs at the recommended dose of 2 mg/kg body weight, 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 a higher concentration than in plasma.

In cattle, marbofloxacin is eliminated slowly in pre-ruminating calves (t½β = 5-9 h) but faster in ruminant cattle (t½β = 4-7 h) predominantly in the active form in urine (3/4 in pre-ruminating calves, ½ in ruminants) and faeces (1/4 in pre-ruminating calves, ½ in ruminants).

After a single intramuscular administration in cattle at the recommended dose of 8 mg/kg body weight, the maximum plasma concentration of marbofloxacin (Cmax) is 7.3 µg/ml reached in 0.78 hours (Tmax). Marbofloxacin is eliminated slowly (T1/2 terminal = 15.60 hours).

After intramuscular administration in lactating cows, a maximum concentration in the milk of marbofloxacin of 1.02 µg/ml is reached (Cmax after the first administration) after 2.5 hours (Tmax after the first administration).

In pigs, marbofloxacin is eliminated slowly (t½β = 8-10 h) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gluconolactone
Disodium edetate
Metacresol
Monothioglycerol
Water for injections

6.2 Major 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

Store in the original package in order to protect from light.

6.5 Nature and composition of immediate packaging

Amber glass type II vial, closed with bromobutyl rubber stopper and aluminium closure

Package sizes:
Carton box with 1 vial of 100 ml
Carton box with 1 vial of 250 ml
Group packages with :
- 6 vials of 100 ml individually packed in carton boxes
- 6 vials of 250 ml individually packed in carton boxes
- 10 vials of 100 ml individually packed in carton boxes
- 10 vials of 250 ml individually packed in carton boxes
- 12 vials of 100 ml individually packed in carton boxes
- 12 vials of 250 ml individually packed in carton boxes

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

Kela – Kempisch Laboratorium – Kela Laboratoria NV
St. Lenaartseweg 48
2320 Hoogstraten
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 06126/4006

9. DATE OF FIRST AUTHORISATION

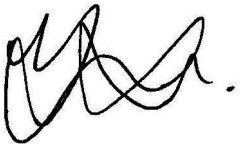
22 April 2013

10. DATE OF REVISION OF THE TEXT

October 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

Veterinary medicinal product subject to veterinary prescription.



Approved: 12 October 2022