LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Boflox 100 mg/ml solution for injection for cattle and pigs
Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Marbofloxacin 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml
6 x 100 ml
6 x 250 ml
10 x 100 ml
10 x 250 ml
12 x 100 ml
12 x 250 ml

5. TARGET SPECIES

Cattle, pigs (sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Intramuscula, subcutaneous or intravenous use
Pigs (sows): Intramuscular use

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
8 mg/kg on a single occasion (IM)
Meat and offal: 3 days
Milk: 72 hours

2 mg/kg for 3 to 5 days (IV/SC/IM)
Meat and offal: 6 days
Milk: 36 hours

Pig (sows):
Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf-life after first opening the container: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material in accordance with local 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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36547/4002

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

LABEL 100 – 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Boflox 100 mg/ml solution for injection for cattle and pigs
Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Marbofloxacin 100 mg/ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs (sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Intramuscular, subcutaneous or intravenous use
Pigs (sows): Intramuscular use

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
8 mg/kg on a single occasion (IM)
Meat and offal: 3 days
Milk : 72 hours

2 mg/kg for 3 to 5 days (IV/SC/IM)
Meat and offal: 6 days
Milk: 36 hours

Pig (sows):
Meat and offal: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Shelf-life after first opening the container: 28 days.
Once broached, use by

11. SPECIAL STORAGE CONDITIONS

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

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

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

Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36547/4002

17. MANUFACTURER'S BATCH NUMBER

Batch:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Boflox 100 mg/ml solution for injection for cattle and 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:
Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

Manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda, 19
E-08950 Esplugues de Llobregat (Barcelona) Spain

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

KELA N.V., St. Lenaartseweg 48, 2320 Hoogstraten, Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Boflox 100 mg/ml solution for injection for cattle and pigs
Marbofloxacin

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

Each ml contains:
Active substance:
Marbofloxacin 100 mg

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

Yellow greenish to yellow brownish, clear solution

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not use in cases of resistance 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.

6. ADVERSE REACTIONS

In very rare cases, transitory inflammatory lesions can occur at the injection site, without clinical impact, when administered via the intramuscular or subcutaneous route.
In very rare cases. administration by the intramuscular route in cattle 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.
However, in cattle, subcutaneous route was shown to be better tolerated locally than 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 displaying adverse reaction(s) during the course of one treatment).
- Common (more than 1 but less than 10 animals in 100 animals).
- Uncommon (more than 1 but less than 10 animals in 1,000 animals).
- Rare (more than 1 but less than 10 animals in 10,000 animals).
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs (sows)

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

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.

In cattle and pig, the preferred injection site is the neck area.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible, to avoid underdosing.

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.

10. WITHDRAWAL PERIODS

Cattle:

Indication	**Respiratory**		**Mastitis**
Dosage	2 mg/kg for 3 to 5 days (IV/IM/SC)	8 mg/kg on a single occasion (IM)	2mg/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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

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.

Pregnancy and lactation:

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 and 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.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

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.

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 product should be disposed of in accordance with local requirements.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2021

15. OTHER INFORMATION

Pack sizes:
Carton box with 1 vial of 100 ml
Carton box with 1 vial of 250 ml
Carton box with 6 vials of 100 ml
Carton box with 6 vials of 250 ml
Carton box with 10 vials of 100 ml
Carton box with 10 vials of 250 ml
Carton box with 12 vials of 100 ml
Carton box with 12 vials of 250 ml

Not all pack sizes may be marketed.

Approved 29 January 2021