LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbim 100 mg/ml Solution for Injection for cattle and pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:

Marbofloxacin	100 mg

Excipients:

Metacresol	2.0 mg
Monothioglycerol	1.0 mg
Disodium edetate (E 386)	0.1 mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Cattle and Pigs (sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Solution for Injection
The recommended dosage is 2 mg/kg/day (1 ml/50 kg) in a single daily injection by intramuscular, subcutaneous or intravenous routes in cattle and by intramuscular route in pigs.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Treatment durations are 3 days in pigs and 3 to 5 days in cattle.

In order to reduce the risk of particulate contamination of the product, it is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.
The septum should not be punctured more than 35 times.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle: Meat and offal: 6 days.
Milk: 36 hours

Pigs: Meat and offal: 4 days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:
Shelf life after first opening the immediate packaging: 28 days.
Once broached, use by: [ ]

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton 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

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4004

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbim 100 mg/ml Solution for Injection for cattle and pigs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:

Marbofloxacin	100 mg

Excipients:

Metacresol	2.0 mg
Monothioglycerol	1.0 mg
Disodium edetate (E 386)	0.1 mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Cattle and Pigs (sows).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Solution for Injection.
i.m., s.c. or i.v. routes in cattle and by i.m. in pigs.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle: Meat and offal: 6 days.
Milk: 36 hours

Pigs: Meat and offal: 4 days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton 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

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4004

17. MANUFACTURER'S BATCH NUMBER

Batch:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Marbim 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

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbim 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:

Metacresol	2.0 mg
Monothioglycerol	1.0 mg
Disodium edetate (E 386)	0.1 mg

A clear yellow solution, free of any particulate matter.

4. INDICATION(S)

In Cattle:
Treatment of respiratory infections caused by sensitive strains of *Pasteurella multocida*, *Mannheimia haemolytica* and *Mycoplasma bovis*.
Treatment of acute mastitis caused by *E. coli* strains sensitive to marbofloxacin during the lactation period.

In Pigs (sows):
Treatment of Metritis Mastitis Agalactia syndrome (postpartum dysgalactia syndrome, PDS) caused by susceptible strains of organisms.

5. CONTRAINDICATIONS

Do not use for bacterial infections with resistance to other fluoroquinolones (cross resistance).

Do not administer in animals with known hypersensitivity to marbofloxacin or any other quinolone or to any of the excipients.

6. ADVERSE REACTIONS

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.
However, in cattle, the subcutaneous route was shown to be better tolerated locally than intramuscular route. Therefore, the subcutaneous route is recommended in heavy cattle.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and Pigs (sows)

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

The recommended dosage is 2 mg/kg/day (1 ml/50 kg) in a single daily injection by intramuscular, subcutaneous or intravenous routes in cattle and by intramuscular route in pigs.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Treatment durations are 3 days in pigs and 3 to 5 days in cattle.

In order to reduce the risk of particulate contamination of the product, it is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.
The septum should not be punctured more than 35 times.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIODS

Cattle: Meat and offal: 6 days.
Milk: 36 hours

Pigs: Meat and offal: 4 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the vial and carton 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 warnings for each target species:
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 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.

User warnings:
- People with known hypersensitivity to (fluoro)quinolones, or any of the excipients, should avoid contact with the product.
- Avoid contact of the skin and eyes with the product. In case of accidental spillage onto skin or eyes, rinse the affected area with plenty of clean water.
- Avoid accidental self-injection, since this can cause local irritation. In case of self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use.

Pregnancy and lactation:
Can be used during pregnancy.
May be used in lactating cows and sows.
No teratogenic, embryotoxic or maternotoxic effects of marbofloxacin have been shown in experiments with laboratory animals.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
No severe side-effects are to be expected at doses up to 3 or 5 times the recommended dose in cattle and pigs respectively. In particular, no lesions of the articular joints are encountered.
Overdose may cause acute signs in the form of neurological disorders which would have to be treated symptomatically.

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

MA number: 50146/4004
Commercial presentations: 50 ml and 100 ml.
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

België/Belgique/Belgien
{Nom/Naam/Name}
<{Adresse/Adres/Anschrift }
BE-0000 {Localité/Stad/Stadt}>
Tél/Tel: + {N° de téléphone/Telefoonnummer/ Telefonnummer}
<{E-mail}>

Deutschland
{Name}
<{Anschrift}
DE-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Österreich
{Name}
<{Anschrift}
A-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

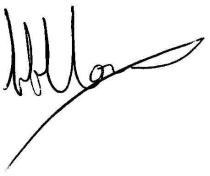
España
{Nombre}
<{Dirección}
ES-00000 {Ciudad}>
Tel: + {Teléfono}
<{E-mail}>

France
{Nom}
<{Adresse}
FR-00000 {Localité}>
Tél: + {Numéro de téléphone}
<{E-mail}>

Ireland
{Name}
<{Address}
IE - {Town} {Code for Dublin}>
Tel: + {Telephone number}
<{E-mail}>

Italia
{Nome}
<{Indirizzo}
IT-00000 {Località}>
Tel: + {Numero di telefono}>

United Kingdom
{Name}
<{Address}
{Town} {Postal code} – UK>
Tel: + {Telephone number}
<{E-mail}>



Approved 23 September 2019