ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 30 mg tablets for dogs
Ibaflin 150 mg tablets for dogs
Ibaflin 300 mg tablets for dogs
Ibaflin 900 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of Ibaflin contains:

Active substance(s)

Ibafloxacin 30 mg
Ibafloxacin 150 mg
Ibafloxacin 300 mg
Ibafloxacin 900 mg

Excipients

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use

Ibaflin is indicated for the treatment of the following conditions in dogs:
Dermal infections (pyoderma – superficial and deep, wounds, abscesses) caused by susceptible strains of *Staphylococci, E. coli*, and *Proteus mirabilis*.
Acute, uncomplicated urinary tract infections, caused by susceptible strains of *Staphylococci, Proteus spp., Enterobacter spp., E. coli* and *Klebsiella spp.*
Respiratory tract infections (upper tract) caused by susceptible strains of *Staphylococci, E. coli*, and *Klebsiella spp.*

4.3 Contraindications

Do not use in dogs during the period of growth as articular cartilage may be affected. This period depends on the breed. For the majority of breeds the use of ibafloxacin is contra-indicated in dogs less than 8 months of age and in giant breeds less than 18 months.
Do not use in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in dogs with a history of seizures.

4.4 Special warnings for each target species

Do not use in dogs with known quinolone hypersensitivity.

4.5 Special precautions for use

Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antibiotic. Ibaflin should only be used based on susceptibility testing.

Special precautions for use in animals

Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.

Special precautions to be taken by the person administering the product
Persons with known hypersensitivity to quinolones should avoid any contact with the product.
Medicinal advice should be sought in the event of accidental ingestion, particularly by a child.

4.6 Adverse reactions (frequency and seriousness)

Diarrhoea, soft faeces, vomiting, dullness and anorexia have been observed with low frequency. These effects were mild and transient.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy. The safety of the veterinary medicinal product has not been established during lactation.

The influence on fertility in male breeding dogs has not been studied.

4.8 Interaction with other medicinal products and other forms of interaction

Fluoroquinolones should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in dogs with a history of seizures. Antacids can interfere with gastro-intestinal absorption of quinolones. Antagonism may be observed with nitrofurantoin.

4.9 Posology and method of administration

Oral use, 15 mg ibafloxacin/kg once daily. The duration of treatment depends on the nature and severity of the infection and on the response. In most cases, a 10-day treatment course will be sufficient. If necessary and depending on the clinical response, treatment can be continued until the response is considered to be adequate. The treatment should be reconsidered if at 5 days no improvement in the clinical condition is observed. If in cases of deep pyoderma, sufficient improvement is not seen after a treatment course of 21 days, it is recommended that the treatment is reconsidered.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The following dosage scheme is advised:

Body weight (kg)	Dosage (number of tablets)				mg administered
	Ibaflin 30 mg	Ibaflin 150 mg	Ibaflin 300mg	Ibaflin 900 mg	
1	0.5				15
2	1				30
3	1.5				45
4	2				60
5		0.5			75
6-10		1			150
11-15		1.5			225

16-20			1		300
21-30				0.5	450
31-40			2		600
41-60				1	900

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

Target animal safety studies in dogs of 8 months of age demonstrated that, when administered orally at 45 mg/kg/day (three times the recommended dose) for a period of 90 days, ibafloxacin produced no observable adverse effects.
No specific antidotes for ibafloxacin (or other quinolones) are known, therefore, in case of overdosage symptomatic treatment should be given.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PARTICULARS

Pharmacodynamic properties

Pharmacotherapeutic group: antibacterial quinolone ATCvet code: QJ 01 MA
Ibaflin contains ibafloxacin as active ingredient. Ibafloxacin is a synthetic antimicrobial substance of the fluoroquinolone class.
Ibafloxacin is a broad spectrum, bactericidal antibiotic. Its action results from inhibition of bacterial DNA gyrase. The most abundant metabolite is 8-hydroxy-ibafloxacin, which is also microbiologically active. Ibafloxacin and 8-hydroxy-ibafloxacin act synergystically. For ibafloxacin (parent compound), MIC values ranging from 0.032 – 0.5 µg/ml are observed for canine isolates of *E. coli, Staphylococcus spp., Proteus mirabilis,* strains of *Pasteurella spp.* and *Salmonella spp.*
A strain which is resistant to a fluoroquinolone will also be resistant to other members of the class of fluoroquinolones.

Pharmacokinetic particulars

After oral administration in dogs, ibafloxacin is rapidly absorbed with maximum plasma levels of microbiologically active compounds obtained at 1-2 hours after administration. Terminal plasma half-life is approximately 4-5 hours. Ibaflin can be administered at any time of the day without consequences for efficacy. However, it is preferred to administer the tablet at feeding time to ensure maximal bioavailability.
The main excretory route is via urine and faeces. After multiple oral administration, steady state is reached after the first or second dosing and no accumulation or induction of biotransformation enzymes occurs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Yeast
Starch
Cellulose
Lactose
Sodium laurylsulphate
Silica
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

150mg and 300mg tablets: 4 years
30mg and 900mg tablets: 3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

30 mg tablets: - Carton box with 20 or 100 tablets in PVC/aluminium heat sealed blisters
150 mg tablets: - Carton box with 10, 20 or 100 tablets in PVC/aluminium heat sealed blisters
- Carton box with 10, 20 or 100 tablets in PVC/PVDC/aluminium blisters
300 mg tablets: - Carton box with 8, 16 or 80 tablets in PVC/aluminium heat sealed blisters
- Carton box with 8, 16 or 80 tablets in PVC/PVDC/aluminium blisters
900 mg tablets: - Carton box with 5, 25 or 50 tablets in PVC/aluminium heat sealed blisters.

6.6 Special precautions for the disposal of unused medicinal 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.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. Marketing Authorisation number(s)

EU/2/00/022/001-008
EU/2/00/022/013-017

9. Date of first authorisation/renewal of the authorisation

08.07.2005 / 26.05.2010

10. Date of revision of the text

26.05.2010

Detailed information on this product is available on the website of the European Medicines Agency (EMA) http://www.ema.europa.eu/.

Prohibition of sale, supply and/or use

Not applicable.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 3% oral gel for dogs and cats
Ibaflin 7.5% oral gel for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each (pre-filled syringe of) Ibaflin Oral Gel contains:

Active substance(s)

Ibaflin 3% Oral Gel: 30 mg of ibafloxacin per g of gel (equivalent to 30.9 mg/ml);
Ibaflin 7.5% Oral Gel: 75 mg of ibafloxacin per g of gel (equivalent to 78.8 mg/ml)

Excipients

Methyl parahydroxybenzoate (0.125%)

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral gel

4. CLINICAL PARTICULARS

Target species

Dogs and cats

4.2 Indications for use

Ibaflin gel is indicated in dogs for the treatment of the following conditions:

- Dermal infections (pyoderma – superficial and deep, wounds, abscesses) caused by susceptible pathogens such as *Staphylococcus spp, E. coli and Proteus mirabilis*.

Ibaflin gel is indicated in cats for treatment of the following conditions:

- Dermal infections (soft tissue infections – wounds, abscesses) caused by susceptible pathogens such as *Staphylococcus spp, E. coli, Proteus spp.* and *Pasteurella spp.*

- Upper respiratory tract infections caused by susceptible pathogens such as *Staphylococcus spp, E. coli, Klebsiella spp.* and *Pasteurella spp*.

4.3 Contraindications

No information is available on the influence of ibafloxacin on developing articular cartilage in the cat during the period of rapid growth as articular cartilage may be affected. Therefore, ibafloxacin should not be used in cats aged less than 8 months. In dogs, this period depends on the breed. For the majority of breeds, the use of ibafloxacin is contra-indicated in dogs less than 8 months of age and in giant breeds less than 18 months old.

Ibaflin 7.5% Oral Gel should not be used in cats.

4.4 Special warnings for each target species

Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and treat the animal accordingly.
The influence on fertility in male breeding animals has not been investigated.

4.5 Special precautions for use

Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions that have responded poorly, or are expected to respond poorly, to other classes of antibiotics. Ibaflin gel should only be used based on susceptibility testing. Do not use in dogs and cats with known quinolone hypersensitivity.

Special precautions for use in animals
In order to avoid any cross contamination, the same syringe should not be used for different animals. Once a syringe is opened it should only be used to continue the treatment course in the same animal.

Special precautions to be taken by the person administering the product
Persons with known hypersensitivity to quinolones should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Diarrhoea, soft faeces, vomiting, dullness, anorexia and salivation were observed with low frequency. These effects were mild and transient.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy in dogs. The safety of the veterinary medicinal product has not been established in pregnant cats and in lactating dogs and cats.

4.8 Interaction with other medicinal products and other forms of interaction

Fluoroquinolones should not be used in combination with non-steroidal anti-inflammatory drugs (NSAIDs) in dogs with a history of seizures. Anti-acids can interfere with gastro-intestinal absorption of quinolones. Antagonism may be observed with nitrofurantoin.

4.9 Posology and method of administration

Oral use, 15 mg ibafloxacin/kg bodyweight once daily.

Cats and dogs	Ibaflin 3% Oral Gel	0.5 ml of gel per kg body weight
Dogs	Ibaflin 7.5% Oral Gel	1 ml of gel per 5 kg body weight.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger (steps of 0.5 ml for the 15 ml syringe and 1.0 ml for the 30 ml syringe).

The gel should be administered at the time of feeding.
The duration of treatment depends on the nature and severity of the infection and on the response seen. In most cases, a 10-day treatment course will be sufficient. If necessary and depending on the clinical response, treatment can be continued until the response is considered to be adequate. The treatment should be reconsidered if after 5 days no improvement in the clinical condition is observed.
If in cases of deep pyoderma, sufficient improvement is not seen after a treatment course of 21 days, it is recommended that the treatment is reconsidered.

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

When administered orally at 75 mg/kg/day (five times the recommended dose) for a period of 90 days in dogs, ibafloxacin was well tolerated. When administered over a period of 30 days to healthy cats, Ibaflin oral gel produced vomiting/regurgitation and salivation at doses of 15 to 75 mg/kg.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PARTICULARS

Ibaflin gel contains ibafloxacin as active ingredient. Ibafloxacin is a synthetic antimicrobial substance of the fluoroquinolone class.

Pharmacodynamic properties

Pharmacotherapeutic group: antibacterial quinolone ATCvet code: QJ 01 MA 96
Ibafloxacin is a broad spectrum antibiotic with bactericidal action resulting from inhibition of bacterial DNA gyrase. The most abundant metabolite is 8-hydroxy-ibafloxacin, which is also microbiologically active. Ibafloxacin and 8-hydroxy-ibafloxacin act synergistically. For ibafloxacin (parent compound), MIC values ranging from 0.032 – 0.5 µg/ml are observed for canine isolates of *E. coli, Staphylococcus spp. and Proteus mirabilis.* In cats, relevant susceptible micro-organisms are *E.coli, Staphylococcus spp., Pasteurella spp., Proteus spp.* and *Klebsiella spp.* (MIC < 0.5 µg ibafloxacin/ml).

Pharmacokinetic particulars

After oral administration to cats, ibafloxacin is rapidly absorbed with maximal plasma levels observed at 1 hour when administered without food and 2 hours when administered with food. In dogs the maximum plasma levels were observed at 2 hours when administered with or without food. Terminal plasma half-life is approximately 3-5 hours. The overall absorption was higher in dogs and cats when administered with food. The main excretory routes are via urine and faeces.
After repeated oral administration, steady state is reached after the first dosing and no accumulation occurs in dogs whereas-modest accumulation is observed in cats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (0.125%)
Potassium dihydrogen phosphate
Disodium hydrogen phosphate dihydrate
Carbomer (carbopol 974 NF)
Sodium hydroxide solution
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

3 years
Shelf-life after first opening: 8 weeks

6.4 Special precautions for storage

Do not store above 25°C.

Any syringes containing unused product should be disposed of once a course of treatment has been completed.

6.5 Nature and contents of container

White adjustable multidose pre-filled syringe consisting of high density polyethylene (HDPE, barrel, plunger and ring) and low density polyethylene (LDPE, cap and seal).

- carton box with 1 x 15 ml (0.5 ml steps) pre-filled syringe (Ibaflin 3% Oral Gel)
- carton box with 5 x 15 ml (0.5 ml steps) pre-filled syringes (Ibaflin 3% Oral Gel)
- carton box with 1 x 30 ml (1 ml steps) pre-filled syringe (Ibaflin 7.5% Oral Gel)
- carton box with 5 x 30 ml (1 ml steps) pre-filled syringes (Ibaflin 7.5% Oral Gel)

6.6 Special precautions for the disposal of unused medicinal product or waste materials, if any

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

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. Marketing Authorisation number(s)

EU/2/00/022/09-12

9. Date of first authorisation/renewal of the authorisation

08.07.2005 / 26.05.2010

10. Date of revision of the text

26.05.2010

Detailed information on this product is available on the website of the European Medicines Agency (EMA) http://www.ema.europa.eu/.

Prohibition of sale, supply and/or use

Not applicable.

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

D. STATEMENT OF THE MRLs

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Tablets
Intervet GesmbH
Siemensstrasse 107
A-1210 Wien
Austria

Oral Gel

Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

D. STATEMENT OF THE MRLs

Not applicable

ANNEX III

LABELLING AND PACKAGE INSERT

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

IBAFLIN TABLETS 30, 150, 300 AND 900 MG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 30 mg tablets for dogs
Ibaflin 150 mg tablets for dogs
Ibaflin 300 mg tablets for dogs
Ibaflin 900 mg tablets for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ibafloxacin

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

20 tablets / 100 tablets
10 tablets / 20 tablets / 100 tablets
8 tablets /16 tablets / 80 tablets
5 tablets /25 tablets / 50 tablets

5. TARGET SPECIES

Dogs

6. INDICATIONS

Pyoderma (superficial and deep), wounds, abscesses, acute uncomplicated urinary tract infections and upper respiratory tract infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use, 15 mg per kg bodyweight once daily.
Read the package insert before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use during the period of growth or in combination with nonsteroidal anti-inflammatory drugs (NSAIDs) in dogs with a history of seizures. Do not use in dogs with a weight of less than 3 kg. Ibafloxacin should only be used based on susceptibility testing. Do not use in dogs with known quinolone hypersensitivity.
Read the package insert before use.

10. EXPIRY DATE

(Month/year)

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only. Veterinary medicinal product subject to prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Name and address of the Marketing Authorisation Holder
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/022/001-008
EU/2/00/022/013-017

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX FOR 1 SYRINGE IBAFLIN 3% ORAL GEL / CARTON BOX FOR 5 SYRINGES IBAFLIN 3% ORAL GEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 3% oral gel for dogs and cats.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ibafloxacin

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

1 adjustable pre-filled multidose syringe, containing 15 ml / Carton box containing 5 adjustable pre-filled multidose syringes, each containing 15 ml Ibaflin 3% oral gel.

5. TARGET SPECIES

Dogs and cats

6. INDICATIONS

Ibaflin gel is indicated in dogs for the treatment of the following conditions:

- Dermal infections (pyoderma – superficial and deep, wounds, abscesses) caused by susceptible pathogens such as *Staphylococcus spp., E. coli* and *Proteus mirabilis.*

Ibaflin gel is indicated in cats for treatment of the following conditions:

- Dermal infections (soft tissue infections – wounds, abscesses) caused by susceptible pathogens such as *Staphylococcus spp., E. coli, Proteus spp.* and *Pasteurella spp.*

- Upper respiratory tract infections caused by susceptible pathogens such as *Staphylococcus spp., E. coli, Klebsiella spp.* and *Pasteurella spp*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use, 15 mg per kg bodyweight once daily.
15 mg per kg bodyweight = 0.5 ml of gel per kg bodyweight
Read the package insert before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use during the period of growth. Ibaflin gel should be used based on susceptibility testing. Do not use in dogs and cats with known quinolone hypersensitivity.
Read the package insert before use.

10. EXPIRY DATE

(Month/year)
Once opened use within 8 weeks

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only. Veterinary medicinal product subject to prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Name and address of the Marketing Authorisation Holder
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/022/09
EU/2/00/022/10

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX FOR 1 SYRINGE IBAFLIN 7.5% ORAL GEL / CARTON BOX FOR 5 SYRINGES IBAFLIN 7.5% ORAL GEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 7.5% oral gel for dogs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ibafloxacin

3. PHARMACEUTICAL FORM

Oral gel

4. PACKAGE SIZE

Carton box containing 1 adjustable pre-filled multidose syringe, containing 30 ml Ibaflin 7.5% oral gel. /
Carton box containing 5 adjustable pre-filled multidose syringes, containing 30 ml Ibaflin 7.5% oral gel.

5. TARGET SPECIES

Dogs

6. INDICATIONS

Ibaflin gel is indicated in dogs for the treatment of the following conditions:

- Dermal infections (pyoderma – superficial and deep, wounds, abscesses) caused by susceptible pathogens such as *Staphylococcus spp.*, *E. coli* and *Proteus mirabilis.*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use, 15 mg per kg bodyweight once daily.
15 mg per kg bodyweight = 1 ml of gel per 5 kg bodyweight
Read the package insert before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in cats.

Do not use during the period of growth. Ibaflin gel should be used based on susceptibility testing. Do not use in dogs with known quinolone hypersensitivity.
Read the package insert before use.

10. EXPIRY DATE

(Month/year)
Once opened use within 8 weeks.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only. Veterinary medicinal product subject to prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Name and address of the Marketing Authorisation Holder

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/022/11
EU/2/00/022/12

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

IBAFLIN TABLETS 30, 150, 300 AND 900 MG

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 30 mg tablets for dogs
Ibaflin 150 mg tablets for dogs
Ibaflin 300 mg tablets for dogs
Ibaflin 900 mg tablets for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

30 mg of ibafloxacin per tablet
150 mg of ibafloxacin per tablet
300 mg of ibafloxacin per tablet
900 mg of ibafloxacin per tablet

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

20 or 100 tablets
10, 20 or 100 tablets
8, 16 or 80 tablets
5, 25 or 50 tablets

4. ROUTE(S) OF ADMINISTRATION

Oral use, 15 mg per kg bodyweight once daily.
Read the package insert before use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP {month/year}>

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

IBAFLIN 3% ORAL GEL ADJUSTABLE MULTIDOSE SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 3% oral gel for dogs and cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

30 mg of ibafloxacin per ml of gel

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

15 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use, 15 mg per kg bodyweight once daily (i.e. 0.5 ml of gel per kg body weight).
Read the package insert before use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP {month/year}>
Once opened use within 8 weeks.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

IBAFLIN 7.5% ORAL GEL ADJUSTABLE MULTIDOSE SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 7.5% oral gel for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

75 mg of ibafloxacin per ml of gel

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

30 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use, 15 mg per kg bodyweight once daily (i.e. 1 ml of gel per 5 kg body weight).
Read the package insert before use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP {month/year}>
Once opened use within [ ] weeks.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE INSERT

PACKAGE INSERT FOR INCLUSION WITH THE IBAFLIN TABLETS

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

Name and address of the Marketing Authorisation Holder
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Name and address of the Manufacturing Authorisation Holder responsible for batch release

Intervet GesmbH.
Siemensstraße 107
1210 Vienna
Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 30 mg tablets for dogs
Ibaflin 150 mg tablets for dogs
Ibaflin 300 mg tablets for dogs
Ibaflin 900 mg tablets for dogs

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

Ibaflin 30 mg: ibafloxacin 30 mg
Ibaflin 150 mg: ibafloxacin 150 mg
Ibaflin 300 mg: ibafloxacin 300 mg
Ibaflin 900 mg: ibafloxacin 900 mg

4. INDICATIONS

Ibaflin is indicated for the treatment of the following conditions in dogs:
Dermal infections (pyoderma – superficial and deep, wounds, abscesses) caused by susceptible strains such as S*taphylococci, E. coli, Proteus mirabilis.*
Acute, uncomplicated urinary tract infections, caused by susceptible strains such as S*taphylococci, Proteus spp., Enterobacter spp., E. coli* and *Klebsiella spp.*
Respiratory tract infections (upper tract) caused by susceptible strains of S*taphylococci, E. coli*, and *Klebsiella spp.*

5. CONTRAINDICATIONS

Do not use in dogs during the period of growth as articular cartilage may be affected. This period depends on the breed. For the majority of breeds the use of ibafloxacin is contra-indicated in dogs less than 8 months of age, and in giant breeds less than 18 months.
Do not use in combination with nonsteroidal anti-inflammatory drugs (NSAIDs) in dogs with a history of seizures.

6. UNDESIRABLE EFFECTS

Diarrhoea, soft faeces, vomiting, dullness and anorexia have been observed with low frequency. These effects are mild and transient.
If you notice any other side effects, please inform your veterinary surgeon.

7. TARGET SPECIES

Dog

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

Oral use, 15 mg ibafloxacin/kg once daily. The duration of treatment depends on the nature and severity of the infection and on the response. In most cases, a 10-day treatment course will be sufficient. If necessary and depending on the clinical response, treatment can be continued until the response is considered to be adequate. The treatment should be re-considered if after 5 days no improvement in the clinical condition is observed.
If, in cases of deep pyoderma, sufficient improvement is not seen after a treatment course of 21 days, it is recommended that the treatment is reconsidered.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The following dosage scheme is advised:

Body weight (kg)	Dosage (number of tablets)				mg. administered
	Ibaflin 30 mg	Ibaflin 150 mg	Ibaflin 300 mg	Ibaflin 900 mg	
1	0.5				15
2	1				30
3	1.5				45
4	2				60
5		0.5			75
6-10					150
11-15		1			225
16-20			1		300
21-30				0.5	450
31-40			2		600
41-60				1	900

9. ADVICE ON CORRECT ADMINISTRATION

Ibaflin can be administered at any time of the day without consequences for efficacy. However, it is preferred to administer the tablet at feeding time to ensure maximal bioavailability.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

Persons with known hypersensitivity to quinolones should avoid any contact with the product. The influence on fertility in male breeding dogs has not been studied.
Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antibiotic. Ibaflin should only be used based on susceptibility testing.
Do not use in dogs with known quinolone hypersensitivity.
Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.
Antiacids can interfere with gastro-intestinal absorption of quinolones. Antagonism may be observed with nitrofurantoin.
The safety of the veterinary medicinal product has not been established during lactation. Ibaflin can be used during pregnancy.

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

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

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

26.05.2010

15. OTHER INFORMATION

Medicinal advice should be sought in the event of accidental ingestion, particularly by a child.
Ibafloxacin is a broad spectrum bactericidal antibiotic from the quinolone group. Its action results from inhibition of bacterial DNA gyrase.
After oral administration in dogs, ibafloxacin is rapidly absorbed with maximum plasma levels of microbiologically active compounds obtained at 1-2 hours after administration. Terminal plasma half-life is approximately 4-5 hours. The main excretory route is via urine and faeces. After multiple oral administration, steady state is reached after the first or second dosing and no accumulation or induction of biotransformation enzymes occurs.
Target animal safety studies in beagle dogs of 8 months of age demonstrated that, when administered orally at 45 mg/kg/day (three times the recommended dose) for a period of 90 days, ibafloxacin produced no observable adverse effects.

PACKAGE INSERT FOR INCLUSION WITH THE 3% ORAL GEL SYRINGE PACKAGES

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

Name and address of the Marketing Authorisation Holder
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Name and address of the Manufacturing Authorisation Holder responsible for batch release

Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 3% oral gel

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

Ibaflin 3% Oral Gel: 30 mg of ibafloxacin per g of gel (equivalent to 30.9 mg/ml);

Excipients

Methyl parahydroxybenzoate (0.125%)

4. INDICATIONS

Ibaflin gel is indicated in dogs for the treatment of the following conditions:

- Dermal infections (pyoderma – superficial and deep, wounds, abscesses) caused by susceptible pathogens such as *Staphylococcus spp., E. coli* and *Proteus mirabilis*

Ibaflin gel is indicated in cats for treatment of the following conditions:

- Dermal infections (soft tissue infections – wounds, abscesses) caused by susceptible pathogens such as *Staphylococcus spp., E. coli, Proteus spp.* and *Pasteurella spp.*
- Upper respiratory tract infections caused by susceptible pathogens such as *Staphylococcus spp., E. coli, Klebsiella spp.* and *Pasteurella spp.*

5. CONTRAINDICATIONS

Do not use in cats up to 8 months of age as no information is available on the influence of ibafloxacin on developing articular cartilage in the cat during the period of rapid growth as articular cartilage may be affected. In dogs, this period depends on the breed. For the majority of breeds, the use of ibafloxacin is contra-indicated in dogs less than 8 months of age, and in giant breeds less than 18 months.

6. UNDESIRABLE EFFECTS

Diarrhoea, soft faeces, vomiting, dullness, and anorexia were observed with low frequency. These effects were mild and transient.

If you notice any other side effect, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats

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

Oral use, 15 mg ibafloxacin/kg once daily.

15 mg per kg bodyweight = 0.5 ml of gel per kg bodyweight

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger (steps of 0.5 ml for the 15 ml syringe).

The duration of treatment depends on the nature and severity of the infection and on the response seen. In most cases, a 10 day-treatment course will be sufficient. If necessary and depending on the clinical response, treatment can be continued until the response is considered to be adequate. The treatment should be reconsidered if at 5 days no improvement in the clinical condition is observed. If in cases of deep pyoderma, sufficient improvement is not seen after a treatment course of 21 days, it is recommended that the treatment is reconsidered.

It is recommended that the gel is administered at the time of feeding.

In order to avoid any cross-contamination, the same syringe should not be used for different animals. Once a syringe is opened it should only be used to continue the treatment course in the same animal.

9. ADVICE ON CORRECT ADMINISTRATION

Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and also treat the animal accordingly.

Quinolones should not be used in combination with nonsteroidal anti-inflammatory drugs (NSAID) in dogs with a history of seizures. Anti-acids can interfere with gastro-intestinal absorption of quinolones. Antagonism may be observed with nitrofurantoin.

Ibafina gel can be used during pregnancy in dogs. The safety of the veterinary medicinal product has not been established in lactating dogs and in pregnant and lactating cats. The influence on fertility in male breeding animals has not been investigated.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.
Do not store above 25°C.
Do not use after the expiry date stated on the label.
Any syringes containing unused product should be disposed of once a course of treatment has been completed.

12. SPECIAL WARNING(S)

Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antibiotic. Ibaflin gel should only be used based on susceptibility testing.

Persons with known hypersensitivity to quinolones should avoid contact with the product.

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

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

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

26.05.2010

15. OTHER INFORMATION

For animal treatment only.

Ibafloxacin is a synthetic antimicrobial substance of the fluoroquinolone class. Ibafloxacin is a broad spectrum antibiotic with bactericidal action resulting from inhibition of bacterial DNA gyrase. The most abundant metabolite is 8-hydroxy-ibafloxacin, which is also microbiologically active . Ibafloxacin and 8-hydroxy-ibafloxacin act synergistically. For ibafloxacin (parent compound), MIC values ranging from 0.032 – 0.5 µg/ml are observed for canine isolates of *E. coli, Staphylococcus spp.* and *Proteus mirabilis.* In cats, relevant susceptible micro-organisms are *E.coli, Staphylococcus spp., Pasteurella spp., Proteus spp.* and *Klebsiella spp.* (MIC ≤ 0.5 µg ibafloxacin/ml).

After oral administration in cats, ibafloxacin is rapidly absorbed with maximum plasma levels observed at 1 hour when administered without food and 2 hours when administered with food. In dogs the maximum plasma levels were observed at 2 hours when administered with or without food. Terminal plasma half-life is approximately 3-5 hours. The overall absorption was higher in dogs and cats when administered with food. The gel should therefore be administered at feeding time to ensure maximal bioavailability. The main excretory routes are via urine and faeces. After multiple oral administration, steady state is reached after the first dosing and no accumulation occurs in dogs whereas modest accumulation is observed in cats.

When administered orally at 75 mg/kg/day (five times the recommended dose) for a period of 90 days in dogs, ibafloxacin was well tolerated. When administered over a period of 30 days to healthy cats, Ibaflin oral gel produced vomiting/regurgitation and salivation at doses of 15 to 75 mg/kg.

PACKAGE INSERT FOR INCLUSION WITH THE 7.5 % ORAL GEL SYRINGE PACKAGES

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

Name and address of the Marketing Authorisation Holder
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Name and address of the Manufacturing Authorisation Holder responsible for batch release

Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ibaflin 7.5% oral gel

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

Ibaflin 7.5% Oral Gel: 75 mg of ibafloxacin per g of gel (equivalent to 78.8 mg/ml)

Excipients

Methyl parahydroxybenzoate (0.125%)

4. INDICATIONS

Ibaflin gel is indicated in dogs for the treatment of the following conditions:

- Dermal infections (pyoderma – superficial and deep, wounds, abscesses) caused by susceptible pathogens such as *staphylococci, E. coli* and *Proteus mirabilis*

5. CONTRAINDICATIONS

Ibaflin 7.5% Oral Gel should not be used in cats.

Do not use in dogs during the period of growth as articular cartilage may be affected. This period depends on the breed. For the majority of breeds the use of ibafloxacin is contra-indicated in dogs less than 8 months of age, and in giant breeds less than 18 months.

6. ADVERSE REACTIONS

Diarrhoea, soft faeces, vomiting, dullness, and anorexia were observed with low frequency. These effects were mild and transient.

If you notice any other side effect, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

Oral use, 15 mg ibafloxacin/kg once daily.

15 mg per kg bodyweight = 1 ml of gel per 5 kg bodyweight

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The syringe should be adjusted to the calculated dosage by setting the ring on the appropriate place on the plunger (steps of 1 ml for the 30 ml syringe).

The duration of treatment depends on the nature and severity of the infection and on the response seen. In most cases, a 10 day-treatment course will be sufficient. If necessary and depending on the clinical response, treatment can be continued until the response is considered to be adequate. The treatment should be reconsidered if at 5 days no improvement in the clinical condition is observed. If in cases of deep pyoderma, sufficient improvement is not seen after a treatment course of 21 days, it is recommended that the treatment is reconsidered.

It is recommended that the gel is administered at the time of feeding.

In order to avoid any cross contamination, the same syringe should not be used for different animals. Once a syringe is opened it should only be used to continue the treatment course in the same animal.

9. ADVICE ON CORRECT ADMINISTRATION

Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and also treat the animal accordingly.

Quinolones should not be used in combination with nonsteroidal anti-inflammatory drugs (NSAID) in dogs with a history of seizures. Anti-acids can interfere with gastro-intestinal absorption of quinolones. Antagonism may be observed with nitrofurantoin.

Ibaflin gel can be used during pregnancy in dogs. The safety of the veterinary medicinal product has not been established in lactating dog. The influence on fertility in male breeding animals has not been investigated.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.
Do not store above 25°C.
Do not use after the expiry date stated on the label.
Any syringes containing unused product should be disposed of once a course of treatment has been completed.

12. SPECIAL WARNING(S)

Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antibiotic. Ibafin gel should only be used based on susceptibility testing.

Persons with known hypersensitivity to quinolones should avoid contact with the product.

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

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

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

26.05.2010

15. OTHER INFORMATION

For animal treatment only.

Ibafloxacin is a synthetic antimicrobial substance of the fluoroquinolone class. Ibafloxacin is a broad spectrum antibiotic with bactericidal action resulting from inhibition of bacterial DNA gyrase. The most abundant metabolite is 8-hydroxy-ibafloxacin, which is also microbiologically active. Ibafloxacin and 8-hydroxy-ibafloxacin act synergistically. For ibafloxacin (parent compound), MIC values ranging from 0.032 – 0.5 µg/ml are observed for canine isolates of *E. coli*, *Staphylococcus spp.* and *Proteus mirabilis.*
In dogs the maximum plasma levels were observed at 2 hours when administered with or without food. Terminal plasma half-life is approximately 3-5 hours. The overall absorption was higher when administered with food. The gel should therefore be administered at feeding time to ensure maximal bioavailability. The main excretory routes are via urine and faeces. After multiple oral administration, steady state is reached after the first dosing and no accumulation occurs in dogs.

When administered orally at 75 mg/kg/day (five times the recommended dose) for a period of 90 days in dogs, ibafloxacin was well tolerated.