ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbax Flavoured *Oral Suspension 30 mg/mL for Dogs and Cats
* to be decided nationally

Orbifloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Orbifloxacin 30 mg/mL
Sorbic acid (E200) 1 mg/mL

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

20 mL

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Not applicable

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral administration. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in cases of known hypersensitivity to orbifloxacin, to other fluoroquinolones or to any of the excipients.

10. EXPIRY DATE

<EXP {month/year}>
Once opened, use by …
Shelf-life after first opening the immediate packaging: 30 days

11. SPECIAL STORAGE CONDITIONS

Store upright. Keep the container in the outer carton.

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

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbax Flavoured *Oral Suspension 30 mg/mL for Dogs and Cats
* to be decided nationally

Orbifloxacin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Not applicable.

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

20 ml

4. ROUTE(S) OF ADMINISTRATION

Oral administration

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

<EXP {month/year}>
Once opened, use by …
Shelf-life after first opening the immediate packaging: 30 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Orbax Flavoured *Oral Suspension 30 mg/mL for Dogs and Cats

*** to be decided nationally**

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

Marketing authorisation holder:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release:
Vet Pharma Friesoythe
Sedelsberger Straße 2
26169 Friesoythe
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbax Flavoured *Oral Suspension 30 mg/mL for Dogs and Cats
* to be decided nationally

Orbifloxacin

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

Orbifloxacin 30 mg/mL suspension

Sorbic acid (E200) 1 mg/mL suspension

Brown, smooth viscous suspension

4. INDICATION(S)

Dogs:
Treatment of uncomplicated bacterial cystitis due to susceptible strains of *E coli* and *Proteus mirabilis,* and treatment of skin and associated soft tissue infections (wounds and abscesses), associated with bacteria susceptible to orbifloxacin.

Cats:
Treatment of skin and associated soft tissue infections (wounds and abscesses), associated with bacteria susceptible to orbifloxacin.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to orbifloxacin, to other fluoroquinolones or to any of the excipients.
Do not use in juvenile dogs during the rapid growth phase (up to 8 month of age in small and medium sized breeds, up to 12 months in large and up to 18 months of age in giant breeds). Quinolones have been shown to cause arthropathy in immature animals, the dog being particularly sensitive to this side-effect.

6. ADVERSE REACTIONS

Mild side effects such as vomiting, soft faeces or diarrhoea may occasionally occur in some dogs and cats. White to yellow faeces was noted in safety studies and was considered to be due to the product. Interruption of treatment is not usually necessary and these effects generally resolve spontaneously without treatment.

Very rare cases of blindness following administration of Orbax have been recorded in cats. Signs may resolve spontaneously but can be permanent.

The frequency of possible adverse effects is defined using the following convention:
Very common (affects more than 1 animal in 10)
Common (affects 1 to 10 animals in 100)
Uncommon (affects 1 to 10 animals in 1,000)
Rare (affects 1 to 10 animals in 10,000)
Very rare (affects less than 1 animal in 10,000)

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats

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

To ensure correct dosage, body weight should be determined as accurately as possible to avoid over- or under-dosing. Use the provided 3 mL syringe to dose 0.5 mL or more of veterinary medicinal product. In very small animals, a dose of less that 0.5 mL may be required. To dose an amount less than 0.5 mL, a 1 mL syringe should be used to improve dosing accuracy.

SHAKE WELL BEFORE USE. Insert the syringe tip into the adaptor opening and invert the bottle. Withdraw the required amount of medication. After use, replace cap, leaving adaptor in the bottle, and rinse the syringe with water.
The veterinary medicinal product should be administered directly into the animal's mouth. The formulation is malt-flavoured and when administered in this fashion in field trials, the medicinal product was accepted by the majority of feline and canine patients.

For the treatment of bacterial cystitis in dogs, the recommended dosage is 2.5 mg/kg bodyweight administered once daily for 10 consecutive days, corresponding to 1 mL of suspension per 12 kg bodyweight.

For the treatment of skin and associated soft tissue infections in dogs or cats, administer 7.5 mg/kg bodyweight administered once daily for 5 to 10 consecutive days, corresponding to 1 mL of suspension per 4 kg bodyweight.

For the treatment of skin and associated soft tissue infections therapy should be continued for at least 2 days beyond cessation of clinical signs. If no improvement is seen within 5 days of starting therapy, the diagnosis should be re-evaluated and a different course of action considered.

9. ADVICE ON CORRECT ADMINISTRATION

BEFORE INITIAL USE, SHAKE VIGOROUSLY for 30 seconds. Remove the cap and inner foil seal and insert the syringe adaptor by pressing firmly into top of bottle.AFTER USE, replace cap, leaving adaptor in the bottle, and rinse the syringe with water.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

The veterinary medicinal product does not require any special temperature storage conditions.
Store upright.
Keep the container in the outer carton.
Shelf-life after first opening the container: 30 days

When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Efficacy of the veterinary medicinal product for the treatment of pyoderma has not been investigated.
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 to other classes of antimicrobials. Whenever possible, fluoroquinolones should only be used based on susceptibility testing.

Safety has not been established in cats less than 11 weeks of age.

The use of fluoroquinolones in cats has been reported to adversely affect the retina at high doses. These effects can be irreversible and blindness can occur. Such products should be used with caution in cats, and the recommended dose should not be exceeded. The bodyweight should be accurately determined before treatment.

The veterinary medicinal product should be used with caution in animals with hepatic and/or renal impairment and the posology should be adapted if necessary.

Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Efficacy of the veterinary medicinal product for the treatment of pyoderma has not been investigated.

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

- Avoid skin and eye contact
- In case of accidental contact with skin, rinse affected area with copious amounts of water.
- In case of accidental contact with eyes, rinse with plenty of clean water.
- Do not handle this product if you have known hypersensitivity against substances in this product or to any other (fluoro)quinolones.
- Do not smoke, eat or drink when handling the veterinary medicinal product.
- Wash hands carefully after administering the veterinary medicinal product.

Pregnancy / Lactation / Fertility:

In laboratory animals (rats, rabbits) studies have shown prenatal/postnatal toxicity and developmental effects. The safety of the veterinary medicinal product has not been established during pregnancy and lactation in dogs and cats.
Therefore, the product should not be used during pregnancy and lactation or in animals intended for breeding.

Interaction with other medicinal products and other forms of interaction:

Concurrent administration with metal cations such as those contained in antacids made with magnesium hydroxide or aluminium hydroxide, or multivitamins containing iron or zinc, has been reported to dramatically decrease the bioavailability of fluoroquinolones.

The dosage of theophylline should be reduced when used concurrently with fluoroquinolones.

Cimetidine has been shown to interfere with the metabolism of fluoroquinolones and should be used with care when used concurrently.

Concurrent administration of fluoroquinolones may increase the action of oral anticoagulants.

Concurrent use of fluoroquinolones with oral cyclosporine is contraindicated.

Overdose (symptoms, emergency procedures, antidotes):

Dogs:
The effects in dogs of overdose have been investigated following dosing at 3x and 5x the dose level at 3x the intended treatment duration, as well as at 10x the dose level for the intended treatment duration. Symptoms observed include gastrointestinal signs such as discolouration of the faeces (white/yellow), emesis, soft and/or mucoid faeces, and at high doses, hypersalivation, reduced food consumption, mild weight loss, glucosuria and lower urine pH. Symptomatic treatment and/or discontinuation of therapy should be considered if intolerance is observed.

Cats:
The effects in cats of overdose have been investigated following dosing at 2x, 3x, 5x, 6x and 10x the dose level at 3x the intended treatment duration. Symptoms observed at the highest dose level included mild gastrointestinal effects such as increased incidence of emesis, salivation, and soft, mucoid, and/or watery feces. A slight decrease in food consumption has been observed. Symptomatic treatment and/or discontinuation of therapy should be considered if intolerance is observed.

Particular attention was paid to ocular safety assessment. There were no electroretinographic changes and no visual deficits observed in any cat. At the exaggerated doses of 45.0 and 75.0 mg/kg/day, minimal ophthalmic changes were noted which consisted of tapetal hyperreflectivity, which correlated histopathologically with swelling of photoreceptor cells. Electron microscopy revealed swollen rod cells with disorganized disc material in the outer photoreceptor segments. If a visual deficit is suspected, discontinue use immediately.

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

20 January 2009

15. OTHER INFORMATION

The veterinary medicinal product (20 mL) is supplied in Amber type 1 glass bottles of nominal volume 25 mL with white polypropylene cap containing 20 mL suspension. A low density polyethylene press in bottle adapter and a 3 mL oral syringe composed of polypropylene with graduations of 0.1 mL are included. The contents are packaged within a partitioned folding carton which houses the bottle and package insert on one side and the PIBA and syringe on the other side.