Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Softiflox 5 mg flavoured chewable tablets for cats and dogs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Chewable Tablet contains:

Active Substance:
Marbofloxacin 5.0 mg

Excipients :
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable Tablet.
Light brown round convex tablet with breakline.

4 CLINICAL PARTICULARS

4.1 Target Species

Cats and dogs.

4.2 Indications for use, specifying the target species

In dogs: Indicated for the treatment of skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis) caused by susceptible strains of organisms, urinary tract infections associated or not with prostatitis caused by susceptible strains of organisms and respiratory infections, caused by susceptible strains of organisms.

In cats: Indicated for the treatment of skin and soft tissue infections (wounds, abscesses phlegmons) and upper respiratory tract infections caused by susceptible strains of organisms.

4.3 Contraindications

Do not use in animals with known hypersensitivity to marbofloxacin or other (fluoro)quinolones or to any of the excipients.

Do not use in dogs and cats with central nervous system (CNS) disorders, such as epilepsy, as fluoroquinolones could potentially cause seizures in predisposed animals

Do not use in dogs aged less than 12 months or less than 18 months for exceptionally large breeds of dogs, such as Great Danes, Briard, Bernese, Bouvier and Mastiffs, with a longer growth period as the fluoroquinolones have been shown to induce erosion of the articular cartilage in juvenile dogs. Not recommended for use in cats aged less than 16 weeks.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) Special precautions for use in animals
A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.
Fluoroquinolones should only 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, use of fluoroquinolones should be based on susceptibility testing. Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used. Superficial and deep skin infections occurs mostly secondary to an underlying disease, thus, it is advisable to determine the underlying cause and to treat the animal accordingly 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 effectiveness of treatment with other quinolones due to the potential for cross-resistance

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to (fluoro)quinolones should avoid any contact with the veterinary medicinal product. In case of accidental ingestion, seek medical advice immediately and show packaging or leaflet to the physician. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Mild side-effects, such as vomiting, decreased or loss of appetite, softening of stools, thirst or a transient increase in activity may occasionally occur. The signs cease spontaneously after treatment and do not necessitate cessation of treatment.

Hypersensitive (allergic) reactions may occur in treated animals. In the case of allergic reaction, the treatment should be withdrawn.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals (rat, rabbit) showed no embryotoxicity, teratogenicity and maternotoxicity with marbofloxacin at therapeutic doses. The safety of the product has not been assessed in dogs and cats during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Fluoroquinolones are known to interact with orally administered cations (Aluminium, Calcium, Magnesium , Iron and Zinc). In such cases bioavailablity may be reduced. Marbofloxacin may antagonize nitrofurantoin, concomitant use is not recommended. Marbofloxacin may increase blood levels of methotrexate and theophylline, and alter phenytoin levels. The dose of Theophylline should be reduced in cases of concomitant administration. In case of glyburide therapy hypoglycemia may occur.

4.9 Amounts to be administered and administration route

For oral administration.

The recommended dose rate is 2 mg/kg per day (1 tablet per 2.5 kg) in a single daily administration.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

DOGS:
In skin and soft tissue infections, treatment is at least 5 days but may be extended up to 40 days depending on the course of the disease.

In urinary infections, treatment is at least 10 days but may be extended up to 28 days depending on the course of the disease.

In respiratory infections, treatment is at least 7 days but may be extended up to 21 days depending on the course of the disease.

The diagnosis should be re-evaluated before extending treatment beyond the minimum recommended treatment period

Cats:
In skin and soft tissue infections (wounds, abcesses and phlegmons) treatment duration is 3 to 5 days. Skin and soft tissue infection treatment efficacy can be improved with wound cleaning and debridement, as well as drainage of abcesses

In upper respiratory infections, treatment duration is 5 days.

Dose Table

Bodyweight (kg)	No. of Tablets
2.5	1
5	2

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

Overdosage may cause cartilage damage in the joints and acute signs in the form of neurological disorders, tremors, which should be treated symptomatically.

Other signs of overdosage can include : anorexia, vomiting, dehydration, red skin, facial swelling, lethargy and weight loss.

In dogs, bloody diarrhoea was observed at 3 times the recommended dose which resolved spontaneously without intervention.

Retinotoxic effects (including blindness) have been reported in cats administered fluorquinolones when the recommended dose is exceeded.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Fluoroquinolones
ATC Vet Code: QJ01MA93

5.1 Pharmacodynamic properties

Marbofloxacin, is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of the DNA gyrase. Marbofloxacin is effective against a wide range of Gram positive bacteria (in particular *Staphylococcus* spp., *Streptococci* spp.) and Gram negative bacteria (*Escherichia coli, Enterobacter cloacae, Serratia marcescens, Proteus* spp., *Klebsiella* spp., *Pasteurella* spp., *Pseudomonas* spp.,) as well as *Mycoplasma* spp..

Resistance to fluoroquinolones occurs by chromosomal mutation leading to changes in three mechanisms that result in changes in the cell wall decreasing permeability, expression of an efflux pump or mutation in the enzymes reducing molecule binding. No significant evolution of resistance has been observed since the launch of marbofloxacin molecule on the veterinary market. The occurrence and rate of genetic transfer of resistance is therefore considered low.

Cross-resistance with β-lactam antibiotics, aminoglycoside, tetracyclines, macrolide and polypeptide antibiotics, sulfonamides, diaminopyrimidines and nitrofurans does not generally occur. However, certain mutation conferring resistance to fluoroquinolones can also confer cross resistance to cephalosporins, tetracylines, macrolides and chloramphenicol.

5.2 Pharmacokinetic properties

After oral administration in dogs and cats at the recommended dose of 2 mg/kg bodyweight, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.20 μg / ml within 2 hours for dogs and 2.4 μg/ml within 30 minutes for cats.

Marbofloxacin is weakly bound to plasma proteins and is extensively distributed. In most tissues, marbofloxacin is found at higher concentrations than in the plasma. Marbofloxacin is slowly eliminated from the body ($t_{1/2}\beta$ = 9.7 hours in dogs and 8.8 hours in cats), predominantly in the active form, in urine and faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Spray dried pork liver powder
Povidone K30
Yeast Extract
Lactose Monohydrate
Crospovidone
Cellulose microcrystalline
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and composition of immediate packaging

Blisters (aluminium/aluminium): 14, 28, 42, 56, 70, 84, 98 and 280 tablets in outer packages with blister strips containing 14 tablets each.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

Norbrook Laboratories Ltd
Station Works
Newry
County Down
Northern Ireland
BT35 6JP

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/140/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd March 2013

10 DATE OF REVISION OF THE TEXT

February 2014