SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Softiflox 80 mg Flavoured Chewable Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Chewable Tablet contains:
Active Substance:
Marbofloxacin 80.0 mg

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

3. PHARMACEUTICAL FORM

Chewable Tablet
Light brown, oval, flat, bevel edged tablet with breakline.
The tablets can be divided into halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dog

4.2 Indications for use, specifying the target species

Marbofloxacin is indicated in dogs 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.

Respiratory infections, caused by susceptible strains of organisms

4.3 Contraindications

Do not use in cats. A 5 mg tablet is available for the treatment of cats.

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 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.

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 activty 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 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 40 kg per day) in a single daily administration.

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

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

Dose Table

Bodyweight (kg)	No. of Tablets
20	½
40	1
60	1½
80	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

Bloody diarrhoea was observed at 3 times the recommended dose which resolved spontaneously without intervention

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL 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 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.

Bioavailability of marbofloxacin is close to 100%. 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), 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.
Any unused half tablets may be stored for 24 hours.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and composition of immediate packaging

Blisters (aluminium/aluminium): 7, 14, 28, 56, 70, 112, 490 tablets in outer packages with blister strips containing 7 tablets each.
Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 Limited
Station Works
Comlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm: 02000/4337

9. DATE OF FIRST OF THE AUTHORISATION

Date: 20 March 2013

10. DATE OF REVISION OF THE TEXT

Date: February 2014

27 February 2014