DRAFT CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Softiflox 80 mg Flavoured Chewable Tablets for Dogs (AT, BE, BG, CY, CZ, DE,EE, EL, ES, HU, IE, IT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK)
Softiflox vet 80 mg Chewable Tablets for Dogs (FI)
Softiflox P 80 mg Chewable Tablets for Dogs (FR)
Softiflox Vet. (DK, NO)
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each Tablet contains:
Marbofloxacin 80 mg

3. PHARMACEUTICAL FORM

Chewable tablet.

4. PACKAGE SIZE

7 / 14 / 28 / 56 / 70 / 112 / 490 Tablets

5. TARGET SPECIES

Dog

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral Administration

8. WITHDRAWAL PERIOD

Not Applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}

Any unused half tablets may be stored for 24 hours.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet

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

FOR ANIMAL TREATMENT ONLY

POM Prescription Only Medicine

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

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

<BN> {number}

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Marbofloxacin

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Softiflox 80 mg Flavoured Chewable Tablets for Dogs
Marbofloxacin

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

Light brown, oval, flat, bevel edged tablet with breakline:
Active Substance
Marbofloxacin 80.0 mg

4. INDICATION(S)

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

5. 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 of the product.

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 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.

6. ADVERSE REACTIONS

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.

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

7. TARGET SPECIES

Dogs

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

For oral administration.

The recommended dose rate is 2 mg/kg per day (1 tablet per 40 kg) in a single daily administration.

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

Dose Table

Bodyweight (kg)	No. of Tablets
20	½
40	1
60	1½
80	2

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 resipiratory 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

9. ADVICE ON CORRECT ADMINISTRATION

Adminster orally.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not use after the expiry date (EXP) stated on the carton and blister.
Any unused half tablets may be stored for 24 hours.

12. SPECIAL WARNINGS

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.
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 upon susceptibilty 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 may increase the prevelance of bacteria resistant the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance
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.
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
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 may occur at 3 times the recommended dose. It disappeared spontaneously and had no effect on the general health of the treated animal.

USER WARNINGS:
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.

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

ManA 2000

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

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

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3. EXPIRY DATE

<EXP {month/year}>

4. BATCH NUMBER

<BN> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.