SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actimarbo 80 mg Flavoured Tablets for Dogs (AT, CZ, DE, ES, IT, NL, PT, SK, UK)
Actimarbo 80 mg Tablets for Dogs (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Marbofloxacin 80.0 mg per tablet

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

3. PHARMACEUTICAL FORM

Tablet.

Off white to beige brown spotted, capsule shaped uncoated tablet with break line on both sides and embossed “MV” and “80” on either side of break line on one side.
The tablets can be divided into halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For dogs, marbofloxacin is indicated in the treatment of:

- Skin and soft tissue infections caused by susceptible strains of organisms.
- Urinary tract infections (UTI) associated or not with prostatitis or epididymitis caused by susceptible strains of organisms.
- Respiratory infections, caused by susceptible strains of organisms.

4.3 Contraindications

Marbofloxacin should not be used 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.
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 case of confirmed or suspected resistance to fluoroquinolones (cross resistance).

Do not use in cats. For the treatment of this species, a 5 mg tablet is available.

4.4 Special warnings for each target species

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.

4.5 Special precautions for use

Special precautions for use in animals

The fluoroquinolones have been shown to induce erosion of articular cartilage in juvenile dogs and care should be taken to dose accurately especially in young animals.

Some fluoroquinolones at high doses may have an epileptogenic potential. Cautious use is recommended in dogs diagnosed as suffering from epilepsy.

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, use of fluoroquinolones should be based on susceptibility testing. 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.

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

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

At the therapeutic recommended dosage, no severe side-effects are to be expected in dogs.
Mild side effects such as vomiting, softening of faeces, modification of thirst or transient increase in activity may occasionally occur. These signs cease spontaneously after treatment and do not necessitate cessation of treatment.

Hypersensitivity (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 (rats, rabbits) showed no teratogenicity, embryotoxicity and maternotoxicity with marbofloxacin at therapeutic doses.
The safety of marbofloxacin has not been assessed in pregnant and lactating dogs.
Use only according to the benefit/risk assessment by the responsible veterinarian in pregnant and lactating animals.

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). In such cases, the bioavailability may be reduced.

Concomitant administration of theophylline requires careful monitoring as serum levels of theophylline may increase.

4.9 Amounts to be administered and administration route

For oral administration.

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

Species	Weight	Dose (Number of tablets per day)				
		Actimarbo 5 mg tablet		Actimarbo 20 mg tablet		Actimarbo 80 mg tablet
Dog	≤ 5 kg	2	OR	½		
	5 - ≤ 10 kg			1		
	10 - ≤ 15 kg			1 ½		
	15 - ≤ 20 kg			2	OR	½
	20 - ≤ 25 kg			2 ½		
	25 - ≤ 30 kg			3		
	30 - ≤ 35 kg			3 ½		
	35 - ≤ 40 kg			4	OR	1
	40 - ≤ 60 kg					1 ½
	60 - ≤ 80 kg					2

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

- in skin and soft tissue infections, treatment duration is at least 5 days. Depending on the course of the disease, it may be extended up to 40 days.
- in urinary tract infections, treatment duration is at least 10 days. Depending on the course of the disease, it may be extended up to 28 days.
- in respiratory infections, treatment duration is at least 7 days and depending on the course of the disease, it may be extended up to 21 days.

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

Overdosage may cause acute signs in the form of neurological disorders, which should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Fluoroquinolones
ATCvet code: QJ01MA93

5.1 Pharmacodynamic properties

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

Marbofloxacin is not active against anaerobes, yeasts or fungi. Cases of resistance have been observed in *Streptococcus*.

The marbofloxacin in vitro activity against canine and feline pathogens isolated in Germany between 2004 and 2006 is good: MIC_{90} values are 0.5 µg/ml for *Staphylococcus pseudointermedius*, 0.03 µg/ml for *Escherichia coli* and 0.06 µg/ml for *Pasteurella multocida*. Strains with MIC ≤ 1 µg/ml are sensitive to marbofloxacin whereas strains with MIC ≥ 4 µg/ml are resistant to marbofloxacin.

Resistance to fluoroquinolones occurs by chromosal mutation with 3 mechanisms: decrease of bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding.

There was no significant development, evolution or spread of resistance in pathogenic strains isolated from diseases in companion animals, since the use of marbofloxacin on the veterinary market. The incidence and the degree of transfer of genetic resistance may be considered as very low.

Cross-resistance to beta-lactam antibiotics, aminoglycosides, tetracyclines, macrolides and polypeptide antibiotics, sulfonamides, nitrofurans and diaminopyrimidines generally does not occur. However, certain mutations causing resistance to marbofloxacin, can also cause resistance against cephalosporins, tetracyclines, macrolides and chloramphenicol.

5.2 Pharmacokinetic particulars

After oral administration in dogs at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5 µg/ml within 2 hours.

Its bioavailability is close to 100%.

It is weakly bound to plasma proteins (less than 10%), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, digestive tract) it achieves higher concentrations than in plasma. Marbofloxacin is eliminated slowly (t½ß = 14 h in dogs) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Cellulose microcrystalline
Povidone K90
Purified water
Crospovidone
Meat flavour
Silica, colloidal anhydrous
Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life of halved tablets: 7 days.

See also section 6.4.

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

In case of using halved tablets: Return any remaining half tablet to the opened blister pocket. Use the remaining half tablet for the next administration.

See also section 6.3.

6.5 Nature and composition of immediate packaging

The product is packaged in aluminium – PVC/aluminium/polyamide blister.
Box of 1 blister of 6 tablets
Box of 2 blisters of 6 tablets
Box of 12 blisters of 6 tablets

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

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 32742/4011

9. DATE OF FIRST AUTHORISATION

July 2013

10. DATE OF REVISION OF THE TEXT

July 2013

PROHIBITION OR SUPPLY SALE AND OR USE

On veterinary prescription only.

APPROVED T. NASH **2/08/13**