PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actimarbo 80 mg Flavoured Tablets for Dogs
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 80 mg of marbofloxacin.

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

6 tablets (1 X 6)
12 tablets (2 X 6)
72 tablets (12 X 6)

5. TARGET SPECIES

Dogs.

6. INDICATIONS

Treatment of skin and soft tissue infections, urinary tract infections associated or not with prostatitis or epididymitis and respiratory tract infections caused by susceptible strains of organisms.

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

Read the package leaflet before use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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

Shelf-life of halved tablets: 7 days.
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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

16. MARKETING AUTHORISATION NUMBERS

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Alu-Alu blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actimarbo 80 mg Flavoured Tablets for Dogs
Marbofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

PACKAGE LEAFLET

Actimarbo 80 mg Flavoured Tablets for Dogs

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

Marketing authorisation holder:

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

or

Accord Healthcare Limited
Sage House
319, Pinner Road
North Harrow
Middlesex HA1 4HF
United Kingdom

2. 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)

Marbofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains 80 mg of marbofloxacin.

4. INDICATIONS

In 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.

5. 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).

6. ADVERSE REACTIONS

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.

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 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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf-life of halved tablets: 7 days.
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.

Do not use after the expiry date stated on the carton and blister after EXP.

12. SPECIAL WARNINGS

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.

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

User warnings
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.

Use during pregnancy or lactation
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.

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.

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

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