PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton, when a pull-out label is not used} AND THE IMMEDIATE PACKAGE {Tub label. When concertina label is used, the front face is also duplicated and attached to the container}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Furosemide Tablets BP (Vet) 40 mg

Furosemide

2. STATEMENT OF ACTIVE SUBSTANCES

Furosemide 40 mg

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

1000 Tablets

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Wear gloves or wash hands immediately after handling tablets. In case of accidental ingestion seek medical attention and show product label and/or package leaflet to the doctor.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {MM/YYYY}

11. SPECIAL STORAGE CONDITIONS

[When a carton is used instead of a pull-out label:] Keep the container in the outer carton.
Store in the original container in order to protect from light.

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

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only. To be supplied only on veterinary prescription.

POM-V

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

Millpledge Ltd
Whinleys Estate
Clarborough
Retford
Nottinghamshire
DN22 9NA

16. MARKETING AUTHORISATION NUMBER

Vm 04409/4000

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

Furosemide Tablets BP (Vet) 40 mg

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

Marketing Authorisation holder:
Millpledge Ltd
Whinleys Estate
Clarborough
Retford
Nottinghamshire
DN22 9NA

Manufacturer responsible for batch release:
Millpledge Ltd
Unit 6/8 Heapham Road Industrial Estate
Gainsborough
Lincolnshire DN21 1RZ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Furosemide Tablets BP (Vet) 40 mg

Furosemide

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

Furosemide 40mg
Oral Tablets containing the stated amount of Furosemide. Flat faced, white circular with bevelled edges and a scored half break line, embossed F40 and plain on the reverse

4. INDICATION(S)

For the treatment of oedema, the product may be used in ascites, hydrothorax, pulmonary oedema of the mammary glands or legs, as well as oedema resulting from cardiac insufficiency, hepatic or renal dysfunction, parasitism or of a traumatic origin.

5. CONTRAINDICATIONS

Do not use in acute glomerular nephritis, in electrolyte diseases, in patients with anuria, or patients that have received excessive doses of cardiac glycosides. Because of the danger of potentiating their toxic effects do no use with aminoglycoside or cephalosporin antibiotics. Allergic reactions have been associated with use with sulphonamides.

6. ADVERSE REACTIONS

The patient may increase its water intake to compensate for the diuresis. Consideration should be given to restricting water intake if the patient's condition makes such a course appropriate.

7. TARGET SPECIES

Cat and dog

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

Oral use. 5mg/KgBW, one or two times per day. For patients weighing less than 8Kg dosage with the 20mg tablet (which may be halved) is recommended. Avoid overdosage in weak and old patients.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original container in order to protect from light.
[When a carton is used instead of a pull-out label:] Keep the container in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the tub. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Prolonged dosage may on occasions justify potassium supplementation and thus monitoring for hypokalaemia should be considered, especially if the product is used in conjunction with cardiac glycosides.
Pregnancy and lactation: The safety of use in pregnancy is not well established and a careful assessment of the likely benefits and potential risks should be made. A deleterious effect on lactation is to be expected, particularly if drinking water is restricted. Furosemide passes into milk, but not to a great extent.
Interactions: Potential interactions with other drugs include ototoxicity with aminoglycosides and nephrotoxicity with cephalosporins. Use in combination with sulphonamide treatment may lead to sulphonamide allergy. There is a possibility of interaction with cardiac glycosides.
Overdose: Dehydration and electrolyte depletion may occur. Monitor and correct as necessary. Dosage higher than that which is recommended, may cause transitory

deafness. Cardiovascular side effects may be observed in weak and old patients following overdose.

Special precautions to be taken by the person administering the medicinal product to animals:
Wear gloves or wash hands immediately after handling tablets. In case of accidental ingestion seek medical attention and show product label and/or pack insert to the doctor.

For Animal Treatment Only

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription.
Vm 04409/4000

Approved: 22/04/21