PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dimazon 50 mg/ml solution for injection

Furosemide

2. STATEMENT OF ACTIVE SUBSTANCES

Furosemide (as the monoethanolamine salt) 50 mg/ml.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml

5 x 10 ml

5. TARGET SPECIES

Pictograms: Cattle, horses, dogs and cats.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous injection in horses and cattle.

For intravenous and intramuscular injection in dogs and cats.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle:

Meat and offal: 28 days.

Milk: 24 hours

Horses:

Not to be used in horses intended for human consumption.

Please refer to package leaflet for further information.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Once broached use within 28 days.

Use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Keep the container in the outer carton in order to protect from light.

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

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:

MSD Animal Health UK Ltd.

Walton Manor, Walton

Milton Keynes MK7 7AJ

Distributor in Northern Ireland:

Intervet Ireland Ltd.

Magna Drive, Magna Business Park,

Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4406

17. MANUFACTURER’S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dimazon 50 mg/ml solution for injection

Furosemide

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Furosemide (as the monoethanolamine salt) 50 mg/ml.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

For IV injection in horses and cattle.

For IV and IM injection for dogs and cats.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle: Milk: 24 hours. Meat and Offal: 28 days.

Horses:

Not to be used in horses intended for human consumption.

Please refer to package leaflet for further information.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

Once broached use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Keep the container in outer carton to protect from light.

POM-V

PACKAGE LEAFLET:

Dimazon 50 mg/ml solution for injection

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

Marketing Authorisation Holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:

Intervet International GmbH

Feldstraße 1a

85716 Unterschleißheim

Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dimazon 50 mg/ml solution for injection

Furosemide

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

Each ml contains 50 mg furosemide (as monoethanolamine salt). It also contains 15 mg benzyl alcohol, 1 mg disodium edetate and 1.8 mg sodium sulfite, anhydrous.

A clear yellowish fluid.

4. INDICATION(S)

A potent saluretic type of diuretic for parenteral administration to cattle, horses, cats and dogs. Dimazon is indicated in the treatment of oedemata associated with cardiac insufficiency, renal dysfunction, trauma and parasitic disease. It is also recommended for the treatment of mammary oedema and limb oedemata.

The product gives rapid onset of diuretic action with increased sodium and water excretion. It is even effective where glomerular filtration is impaired.

5. CONTRAINDICATIONS

Do not use in cases of acute glomerular nephritis, renal failure with anuria, electrolyte deficiency disease or overdosage with digitalis.

Do not use concurrently with aminoglycoside antibiotic treatment.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Too rapid injection in dogs may cause staggering and vomiting.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, horses, dogs and cats.

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

Species	Dosage mg active/kg bodyweight	ml of 50 mg/ml solution	Administration
Horse	0.5 – 1.0 mg i.v.	1-2 ml per 100 kg	1 – 2 times per day, intervals of 6 – 8 hours
Cow	0.5 – 1.0 mg i.v.	1-2 ml per 100 kg	at intervals of 12 – 14 hours
Dog / Cat	2.5 – 5.0 mg i.m./i.v.	0.25 – 0.5 ml per 5 kg body weight	First dose 5mg/kg reduced to 1 – 2mg/kg for maintenance at 6–8 hour intervals

In severe or refractory cases the dose may be doubled on a single occasion in the horse or cow.

The product may be administered observing aseptic precautions:

- by intravenous injection only in cattle and horses.

- by intramuscular or intravenous injection only in cats and dogs.

9. ADVICE ON CORRECT ADMINISTRATION

Do not use if you notice any discolouration of the product..

10. WITHDRAWAL PERIOD(S)

Cattle:

Meat and offal: 28 days.

Milk: 24 hours

Horses:

Not to be used in horses intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.

Keep the container in the outer carton in order to protect from light.

Shelf life after first opening the immediate packaging: 28 days.

When the container is broached / opened for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided on the label.

If the product is stored for a prolonged period below + 18°C, crystalline precipitation may occur. Do not use the product whilst the crystals are present. The crystals may be re-dissolved by shaking the vial and then holding the vial for only 24 hours at 30°C - 40°C. Once the crystals are re-dissolved, the product may be used.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Clinical experience with dogs indicates that improved results can frequently be achieved by supplementary administration of corticosteroids.

Special precautions for use in animals:

In pulmonary oedema of cardiac origin, combined therapy with cardiac glycosides is advisable. Only during prolonged treatment is it necessary to monitor potassium balance. Potassium supplements may be necessary.

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

Care should be taken to avoid accidental self-injection. If irritation occurs, seek medical attention, showing the product label to a doctor. Following skin/eye contamination, wash/irrigate area with clean, running water immediately. Wash hands after use.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Potential interactions with other drugs include ototoxicity with aminoglycosides and nephrotoxicity with cephalosporins.

Use in combination with sulphonamide treatment may lead to sulphonamide allergy.

Overdose (symptoms, emergency procedures, antidotes):

Doses higher than recommended may cause transitory deafness.

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

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. .

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

December 2020

15. OTHER INFORMATION

For animal treatment only.

Pack sizes:

Cartons of 1 x 10 ml and 5 x 10 ml vials.

Not all pack sizes may be marketed

Legal Category:

POM-V

To be supplied only on veterinary prescription.

Marketing authorisation number:

Vm 01708/4406

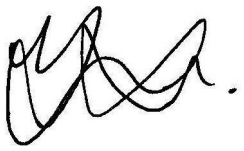
Distributor in Northern Ireland:

Intervet Ireland Ltd.

Magna Drive, Magna Business Park,

Citywest Road,

Dublin 24.



Approved: 30 December 2020