SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dimazon 50 mg/ml Solution for Injection for cattle, horses, cats and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Furosemide (as monoethanolamine salt) 50.00 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	15.00 mg
Disodium edetate dihydrate	1.00 mg
Sodium sulphite anhydrous	1.80 mg
Ethanolamine	
Sodium chloride	
Water for injections	

A clear, yellowish fluid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, cats and dogs.

3.2 Indications for use for each target species

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

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

3.3 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.

The therapeutic effect may be impaired by increased intake of drinking water. So far as the patient's condition allows, the amount of drinking water should be restricted.

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Clinical experience with dogs indicates that improved results can frequently be achieved by supplementary administration of corticosteroids.
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 advice and show the package leaflet or the label to the physician.
Following skin/eye contamination, wash/irrigate area with clean, running water immediately.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle, horses, cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Haemoconcentration; Circulatory Impairment; Hypokalaemia[1], Hyponatraemia[1];

[1] In case of longer therapy.

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Haemoconcentration; Circulatory Impairment; Hypokalaemia[1], Hyponatraemia[1]; Vomiting[2]; Staggering[2]

[1] In case of longer therapy.
[2] Following too rapid injection.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

Cattle and horses: Intravenous use.
Cats and dogs: Intravenous or intramuscular use.

Species	**Dosage mg active/kg bodyweight**	**ml of 50 mg/ml solution**	**Administration**
Horse	0.5 – 1.0 IV	1 – 2 ml per 100 kg	1 – 2 times/day at intervals of 6 – 8 hours
Cattle	0.5 – 1.0 IV	1 – 2 ml per 100 kg	At intervals of 12 – 14 hours
Dog/cat	2.5 – 5.0 IM/IV	0.25 – 0.5 (per 5 kg bodyweight)	First dose 5 mg/kg reduced to 1 – 2 mg/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 veterinary medicinal 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.

Onset and Duration of Action

Species	**Route**	**Time of onset**	**Duration**
Dog	IV or IM	After 10 – 15 minutes	2 – 3 hours

3.10 Symptoms of overdose and where applicable, emergency procedures and antidotes

Doses higher than recommended may cause transitory deafness.
Cardiovascular side effects may be observed in weak and old patients following overdosage.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QC03CA01.

4.2 Pharmacodynamics

Furosemide is a derivative of sulphamoyl-anthranilic acid and is a rapid onset diuretic used in animals and humans. Furosemide acts on the urine producing regions of the nephron and increases the filtration volume while impairing the reabsorption of sodium, chlorine and water. An isotonic or slightly hypotonic urine with unchanged or slightly acid Ph is produced. Potassium excretion is only significantly increased after large doses.

4.3 Pharmacokinetics

Cattle
The absorption of furosemide is rapid but incomplete with maximum plasma levels occurring within 1 hour of dosing depending on the administration route.
Furosemide is not accumulated after repeated dosing as evidenced by comparison of plasma profiles and of tissues concentrations.

The volume of distribution is relatively low, indicating limited distribution into tissues (mainly liver and kidney), also reflecting the extensive plasma protein binding. Absorption and tissue distribution are extremely fast in cattle after intramuscular administration. In plasma, maximum levels range from 15 minutes to 1.5 hours, and the half-life is 0.22 - 2.7 hours. Elimination is predominantly renal via urine and is clearly

prolonged after oral and intramuscular administration compared to intravenous administration (probably because of delayed absorption). Lesser quantities are eliminated via faeces and very little via milk (half-life 3 hours). Only small quantities are excreted in the bile. The majority of the total dose is excreted within 24 hours.

Horse
The apparent volume of distribution is 0.66 L/kg in horses. The elimination half-life is prolonged after intramuscular administration compared with intravenous administration (65 - 86 vs 25 - 39 minutes, respectively), probably on account of delayed absorption. The half-life of 7.6 hours from the urine points to a distribution to poorly perfused tissues. The total clearance is about 12 mL/kg/min and the renal excretion accounts for 60% in unmetabolised form. Plasma protein binding of furosemide in horses in about 95%. Up to 60% of the amount of furosemide injected intravenously is rapidly excreted unchanged in the urine, and furosemide is still detectable in urine for about 12 hours.

Dog and cat
Following parenteral administration, furosemide is rapidly absorbed with maximum plasma levels occurring within 10 - 15 minutes. It is not accumulated after repeated dosing. Plasma half-lives are similar across species after intravenous administration (dog 12 - 24 minutes). Elimination is rapid and predominantly via the kidneys in the urine. The majority of the total dose is excreted within the first 24 hours (after intravenous injection in dogs, about 44 - 56% of the dose are excreted in the urine within one hour and 55 - 69% within 24 hours). The faeces contain 17 - 39% of the dose. Plasma protein binding of furosemide is 91% and estimated distribution volume is 0.52 L/kg. Furosemide metabolises in very small amounts (main metabolite: 4-chloro-5-sulfamoyl-anthranilic-acid, no diuretic activity).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C.
Keep the container in the outer carton in order to protect from light.
If the product is stored for a prolonged period below 18 °C, crystalline precipitation may occur. Do not use the product whilst these crystals are present. The crystals may be redissolved by shaking the vial and then storing it for 24 hours at 30 °C - 40 °C. Once the crystals are redissolved, the product may be used.

Discard unused material.

5.4 Nature and composition of immediate packaging

Clear type I tubular glass vial sealed with a grey type I bromobutyl rubber stopper and aluminium cap with a filling volume of 10 ml.

Pack sizes
Cardboard box of 1 x10 ml or 5 x 10 ml vials.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4091

8. DATE OF FIRST AUTHORISATION

27 April 2005

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall

Approved 20 August 2025