SUMMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dimazon 50 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Furosemide (as monoethanolamine salt)	50.0 mg

Excipients:

Benzyl alcohol	15.0 mg
Disodium edetate	1.0 mg
Sodium sulfite, anhydrous	1.8 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
A clear, yellowish fluid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, cats and dogs.

4.2 Indications for use, specifying the target species

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.

4.3 Contra-indications

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.

4.4 Special warning for each target species

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

4.5 Special precautions for use

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 medicinal product to the 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.

4.6 Adverse reactions (frequency and seriousness)

Too rapid injection in dogs may cause staggering and vomiting.

4.7 Use during pregnancy or lactation

Can be used during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

Species	Dosage mg active/kg bodyweight	ml of 50 mg/ml solution	Administration
Horse	0.5-1.0 i.v.	1-2 ml per 100 kg	1-2 times/day at intervals of 6-8 hours
Cattle	0.5-1.0 i.v.	1-2 ml per 100 kg	At intervals of 12-14 hours
Dog/cat	2.5-5.0 i.m./ i.v.	0.25-0.5 (per 5kg bodyweight)	First dose 5mg/kg reduced to 1-2mg/kg for maintenance at 6-8 hours 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.

Onset and Duration of Action

Species	Route	Time of onset	Duration
Dog	i.v or i.m	after 10-15 minutes	2-3 hours

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

Doses higher than recommended may cause transitory deafness.

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

4.11 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Cardiovascular system, high-ceiling diuretics, sulfonamides, plain; furosemide
ATC vet code: QC03CA01

5.1 Pharmacodynamic properties

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 re-absorption 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.

5.2 Pharmacokinetic particulars

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 i.m. administration. In plasma, maximum levels range from 15 minutes to 1.5 hour, and the half-life is 0.22-2.7 hours. Elimination is predominantly renal via urine, and is clearly prolonged after oral and i.m. administration compared to i.v. administration (probably because 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 i.m. administration compared with i.v. 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 i.v. 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 i.v. 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 i.v. 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 metabolizes in very small amounts (main metabolite: 4-chloro-5-sulfamoyl-anthranilic-acid, no diuretic activity).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Disodium edetate
Sodium sulfite, anhydrous
Ethanolamine
Sodium chloride
Water for Injections

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

Do not store above 25^{o}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^{o}C, crystalline precipitation may occur. Do not use the product whilst these crystals are present. The crystals may be re-dissolved by shaking the vial and then storing it for 24 hours at 30^{o}C – 40^{o}C. Once the crystals are re-dissolved, the product may be used.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

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

Cartons of 1 x 10 ml and 5 x 10 ml vials.
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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

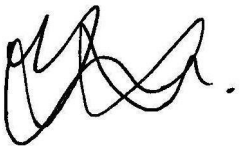
Vm 01708/4406

9. DATE OF FIRST AUTHORISATION

27 April 2005

10. DATE OF REVISION OF TEXT

December 2020



Approved: 30 December 2020