1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dimazon 50 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:
Furosemide (as monoethanolamine salt) 50 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	15.0 mg
Disodium edetate dihydrate	1.00 mg
Sodium sulphite anhydrous	1.80 mg
Ethanolamine	
Sodium chloride	
Water for injection	

A slightly yellowing fluid.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, dogs and cats.

3.2 Indications for use for each target species

Supportive therapy in all cases in which non inflammatory accumulation of fluid of various origins should be reabsorbed from tissue body cavities, joints, tendon sheaths etc. by means of increased diuresis/saluresis e.g., oedema associated with cardiac insufficiency, renal dysfunction, trauma and parasitic disease. It is also recommended for the treatment of mammary oedema and limb oedema.

3.3 Contraindications

Do not use in cases of liver coma, renal deficiency with anuria, electrolyte deficiency (hypokalaemia, hyponatraemia), hypotony and sulfonamide allergy.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:
When cardiac glycosides are used, furosemide should be applied only for the first 3 days.

In dogs after simultaneous use of furosemide and digoxin preparations an undesired increased digoxin-effect may occur. Therefore, it is recommended to reduce the digoxin dose by about 30%-50% or to administer the two drugs on alternative days

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to furosemide should avoid contact with the veterinary medicinal product.

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 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

Aminoglycoside-antibiotics: increase of the ototoxic effect.
Cefalosporins: increase the nephrotoxic effect.
Cardiac glycosides: increase the toxic effect and increase of glycoside concentration in plasma.
Indomethacin: decrease the diuretic effect.
Sulfonamides: increase the risk of sulfonamide allergy

3.9 Administration routes and dosage

Species	mg/kg bodyweight	ml	Route
Horse, cattle	0.5 – 1.0	1-2 ml per 100 kg	i.v
Dog, cat	1.0 – 2.0	0.1 – 0.2 ml per 5 kg	i.m or i.v

In severe cases, the single dose can be doubled.

The recommended doses will be repeated at an interval of 6 – 8 hours or given 2 – 3 times a day.
During the prolonged treatment, it is necessary to monitor the serum electrolyte balance.

Only the intravenous route should be used in cattle and horses.

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 and horses:

Meat and offal: 1 day
Milk: 24 hours

4. PHARMACOLOGICAL IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QC03CA01

4.2 Pharmacodynamics

Furosemide is a potent saluretic. The veterinary product gives rapid onset of diuretic action with increases in sodium and water excretion without the loss of potassium and is effective even in cases where glomerular filtration is impaired.

4.3 Pharmacokinetics

In dogs the diuresis starts after 30 minutes to 2 hours and lasts about 6 hours.
In cats the diuresis starts within 1 - 6 hours.
After oral application furosemide is excreted via the kidneys mostly in unchanged form. The bioavailability is between 60 - 80 %.

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
Protect from light.
In cases of prolonged storage below 18°C crystalline precipitations may occur. This will not have a negative influence on the efficacy of the solution and is reversible after 24 hours storage above 20 °C. Do not use the product while crystals are present.

5.4 Nature and composition of immediate packaging

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

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 or household waste.
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 Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/109/001

8. DATE OF FIRST AUTHORISATION

01 October 1995

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

15 October 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database*:* (https://medicines.health.europa.eu/veterinary).