Summary 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	50 mg
(as monoethanolamine salt)	
Excipients:	
Benzyl alcohol	15.0 mg
Sodium sulphite, anhydrous	1.8 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A slightly yellowing fluid

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, horses, dogs and cats

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use in cases of liver coma, renal deficiency with anuria, electrolyte deficiency (hypokalemia, hyponatremia), hypotony and sulfonamide allergy.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

When cardiac glycosides are used, furosemide should be applied only for the first 3 days.

In dogs after a 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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Due to the diuretic action there may be hemoconcentration and impairment of the circulation.
In cases of longer therapy, hypokalemia and hyponatremia may occur.
Too rapid injection in dogs may cause staggering and vomiting.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

Animal species	mg/kg body weight	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 prolonged treatment, it is necessary to monitor the serum electrolyte balance.

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

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)

Meat and offal: 1 day
Milk: 24 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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 and 80 %.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Monoethanolamine
Benzyl alcohol
Disodium Edetate Dihydrate
Sodium Chloride
Sodium Sulphite, Anhydrous
Water for Injections

6.2 Incompatibilities

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

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 °C.
Keep container in the outer carton in order to protect from light.
In case 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 the crystals are present.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

Intervet Ireland Ltd.,
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/109/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1995
Date of last renewal: 9th July 2010

10 DATE OF REVISION OF THE TEXT

May 2012