1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fumexx 50 mg/ml solution for injection for cattle, horses, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Furosemide 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 (E1519)	15.00 mg
Sodium hydroxide	
Water for injections	

Clear, colourless to yellow solution, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, dogs and cats.

3.2 Indications for use for each target species

Treatment of non-inflammatory oedema, ascites and accumulation of fluid in body cavities of various origins, including oedema associated with cardiac insufficiency and renal dysfunction, where diuretic therapy is clinically indicated.
Supportive treatment of poisonings where induction of diuresis is considered beneficial.

3.3 Contraindications

Do not use in cases of urinary tract obstruction, renal failure with anuria or severe kidney damage.
Do not use in cases of electrolyte deficiency (hypokalaemia, hyponatraemia).
Do not use in cases of hypovolaemia, hypotension, or dehydration.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Therapeutic efficacy may be impaired by increased intake of drinking water. Where the animal's condition permits, water intake should be restricted to physiologically normal levels during treatment.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Animals treated with furosemide should be observed for early signs of electrolyte imbalance such as thirst, oliguria, increased heart rate, lethargy/drowsiness, restlessness. Particular care should be taken in cats, as cats may be more sensitive to furosemide than dogs.
Furosemide should be used with caution in patients with nephropathy, impaired liver function, and diabetes mellitus.
When administered concomitantly with cardiac glycosides, furosemide should only be used during the first 1–3 days and then intermittently.
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:

Furosemide has possible genotoxic properties and there is evidence of carcinogenicity in mice. Skin contact with or accidental injection of the product should be avoided.
Furosemide is a diuretic and influences the fluid and electrolyte balance. Due to the presence of benzyl alcohol the veterinary medicinal product may cause mild local irritation.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. In case of accidental skin exposure, rinse immediately with plenty of water.
People with known hypersensitivity to furosemide or to benzyl alcohol should avoid contact with the veterinary medicinal product.
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], Dehydration[1]

[1] in cases of longer therapy.

Dogs:

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

[1] In cases of longer therapy.
[2] Following 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

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy:
Laboratory studies in rats, mice and rabbits have not produced any evidence of teratogenic effects but have shown evidence of foetotoxic and maternotoxic effects.
Use only according to the benefit-risk assessment by the responsible veterinarian. The use is not recommended during the second trimester of the pregnancy

Lactation:
Furosemide passes into the maternal milk.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Furosemide increases the toxic effects of cardiac glycosides, cephalosporins, lithium salts and aminoglycosides. It also reduces the effects of sympathomimetics and antidiabetic drugs. It increases the potency of coumarin, theophylline and non-depolarizing muscle relaxants. Non- steroidal anti-inflammatory drugs (NSAIDs) reduce the diuretic effect of furosemide. Use with caution in animals receiving glucocorticosteroids that lower potassium levels.

3.9 Administration routes and dosage

Cattle and horses: intravenous use (i.v.) only.
Dogs and cats: intramuscular or intravenous use (i.m. or i.v.).

Species	mg/kg bodyweight	ml	Route	Frequency
Horse, cattle	0.5 – 1.0	1 – 2 ml per 100 kg	i.v	Administered as a single intravenous injection or divided over two administrations
Dog, cat	2.5 – 5.0	0.5 – 1.0 ml per 10 kg	i.m or i.v	Administered as a single injection or divided over two administrations.

Cattle and horses:
The maximum duration of treatment is two consecutive days.

Dogs and cats:
The dose and dosing interval should be adjusted according to the clinical response and tolerability.

Prolonged storage at temperatures below 25°C may cause crystalline precipitation.
Do not use the product if it contains crystalline precipitation.

The stopper may be safely punctured up to 30 times.

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

Dehydration and electrolyte depletion may occur. Monitor and correct as necessary. Dosage higher than recommended may cause transient deafness and CNS effects (lethargy, coma, seizures). Cardiovascular side effects (e.g., hypotension, heart rhythm disorders, collapse) may be observed in weak and old patients following overdose.

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: 2 days.
Milk: 48 hours.

Horses:
Meat and offal: 2 days.

Not authorised for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QC03CA01

4.2 Pharmacodynamics

Furosemide is a sulfonamide derivative with a strong, fast, but short-lasting (6-8 h) saluretic effect. It increases the excretion of sodium and chlorides, but has a weaker effect on the excretion of potassium, magnesium, and calcium. It acts at the level of the thick-walled section of the nephron loop. In the distal convoluted tubules, it increases potassium secretion. Outside the kidneys, it affects carbohydrate metabolism by reducing glucose tolerance. It has a direct spasmolytic effect on the muscular layer of vessels.

4.3 Pharmacokinetics

Furosemide starts working 2-3 minutes after intravenous administration. After administration by other routes (both injection and oral), it is absorbed very quickly, which is the result of its low solubility in lipids. The drug is also excreted from the body very quickly and occurs mainly in urine, in an unchanged state.

The low solubility of furosemide and rapid renal excretion minimize the possibility of its accumulation in tissues and internal organs and crystallization.

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

5.3 Special precautions for storage

Do not refrigerate or freeze.

5.4 Nature and composition of immediate packaging

Amber glass vial (type II) closed with a coated bromobutyl rubber stopper (type I) and aluminium cap in a cardboard box.

Pack sizes:
Cardboard box with 1 vial of 20 mL solution for injection
Cardboard box with 1 vial of 50 mL solution for injection

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 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. MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10980/052/001

8. DATE OF FIRST AUTHORISATION

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

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).