OFFICE FOR REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL DEVICES AND BIOCIDAL PRODUCTS
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(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Fumexx 50 mg/ml solution for injection for cattle, horses, dogs and cats (AT, BE, BG, CY, CZ, EE, EL, ES, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, UK(NI)

Fumexx Vet 50 mg/ml solution for injection for cattle, horses, dogs and cats (DK, FI, IS, NO, SE)

Furosan 50 mg/ml solution for injection for cattle, horses, dogs and cats (DE, FR)

PRODUCT SUMMARY

EU procedure number	PL/V/0114/001/DC
Name, strength and pharmaceutical form	Fumexx 50 mg/ml solution for injection for cattle, horses, dogs and cats (AT, BE, BG, CY, CZ, EE, EL, ES, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, UK(NI) Fumexx Vet 50 mg/ml solution for injection for cattle, horses, dogs and cats (DK, FI, IS, NO, SE) Furosan 50 mg/ml solution for injection for cattle, horses, dogs and cats (DE, FR)
Applicant	Alfasan Nederland B.V. Kuipersweg 9 3449 JA Woerden The Netherlands
Active substance(s)	Furosemide
ATC vetcode	QC03CA01
Target species	Cattle, horse, dog, cat
Indication for use	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.

Please note that the development of the veterinary medicinal product during its lifecycle is reflected in the section “Post-authorisation procedures” of this report, as well as in the current SPC and product information. Therefore, for products that have been authorised for some time, any other part of this document may include outdated information.

PRODUCT INFORMATION

The current Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended
Reference product (RP)	Furosemid 5% inj., 50 mg/ml, roztwór do wstrzykiwań dla bydła, koni, psów i kotów
Marketing authorisation holder	Grabikowski-Grabikowska Przedsiębiorstwo Produkcyjno-Handlowo-Usługowe „INEX" spółka jawna
Marketing authorisation number	1782/07
EU procedure number	n.a.
Date of authorisation	16/10/2007
Date of completion of the original decentralised procedure	05/08/2026
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, NL, NO, PT, RO, SE, SI, SK, UK(NI)
Concerned Member States for subsequent recognition procedure	n.a.
Withdrawn CMS during original decentralised procedure	n.a.

Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES. Additionally, detailed information on protection periods has only been published in PuAR since 09.02.2026.

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains 50.00 mg/ml of furosemide as active substance and benzyl alcohol, sodium hydroxide and water for injections as excipients.

The container/closure system is amber glass vial (type II) closed with a coated bromobutyl rubber stopper (type I) and aluminium cap in a cardboard box.

The choice of the formulation and presence of preservative are justified.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing sites.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

C. Production and control of starting materials

The active substance is furosemide, an established active substance described in the European Pharmacopeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this VMP.

D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

E. Control tests on the finished product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification and their limits have been justified and are considered appropriate to adequately control the quality of the VMP.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability tests

The stability of the active substance is established by the re-test period of 5 years as stated in the Certificate of Suitability.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the VMP throughout its shelf life when stored under the approved conditions. A shelf life of 2 years for the medicinal product is granted.

In-use stability studies have been also performed, and an in-use shelf life of 28 days after first opening the immediate packaging is approved.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of pharmacodynamics/pharmacokinetics, toxicology, single and repeated toxicity, reproductive toxicity, mutagenicity, and carcinogenicity tests are not required.

The safety aspects of this VMP are identical to the reference VMP.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and are adequate to ensure safety of the product to users / the environment / consumers.

The routes of administration are:
Cattle and horses: intravenous (i.v.) use only.
Dogs and cats: intramuscular or intravenous use (i.m. or i.v.).

A. Safety tests

Pharmacological studies

The reference product for this application is authorised via a national procedure in Poland.

Name: FUROSEMID 5% INJ., 50 mg/ml, solution for injection for cattle, horses, dogs and cats Marketing Authorisation Holder: Grabikowski-Grabikowska PPHU "INEX" Sp.j. Marketing Authorisation nr: 1782/07 Marketing Authorisation date: 16-10-2007.

Based on exemption 7.1.a for intravenous use and exemption 7.1.b for intramuscular use, the products can be considered bioequivalent and in-vivo studies may be omitted according to the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.4).

Assuming that bioequivalence with their respective reference products can be accepted, no pharmacological studies are required since it is considered that details have been sufficiently described in the file of the reference product.

Toxicological studies

The reference product for this application is authorised via a national procedure in Poland.

Name: FUROSEMID 5% INJ., 50 mg/ml, solution for injection for cattle, horses, dogs and cats Marketing Authorisation Holder: Grabikowski-Grabikowska PPHU "INEX" Sp.j. Marketing Authorisation nr: 1782/07 Marketing Authorisation date: 16-10-2007.

Based on exemption 7.1.a for intravenous use and exemption 7.1b. for intramuscular use, the products can be considered bioequivalent and in-vivo studies may be omitted according to the guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.4).

Assuming that bioequivalence with their respective reference products can be accepted, no toxicological studies are required since it is considered that details have been sufficiently described in the file of the reference product.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure user safety.

Environmental Risk Assessment

This is a generic application. Given this legal base, the applicant is not required to submit pharmacological, toxicological, safety or efficacy data. However, the applicant submitted an ERA.

Ecotoxicity of the candidate formulation is assessed according to the following relevant guidelines: VICH Guideline GL6: Environmental impact assessment (EIAS) for veterinary medicinal products – Phase I (CVMP/VICH/592/98-FINAL, June 2000) and Revised guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38 (EMEA/CVMP/ERA/418282/2005-Rev. 1). The applicant followed the decision tree and stopped at step 5. It is correctly concluded that the assessment can stop at Phase I since the product is intended only to treat a small number of animals in a herd (horses and cattle) and the product will be used in non-food animals (cats and dogs).

As there are similar products already authorized in the EU, a complete data package for environmental risk assessment is not required. No environmental risk is expected when the product is used, handled and disposed according to the information included in the SPC.

B. Residues documentation

Residue tests

No residue depletion studies were conducted because the Committee for Veterinary Medicinal Products concluded that there is no need to establish an MRL for furosemide and recommended its inclusion in Table 1 of the Annex to Commission Regulation (EU) No 37/2010.

Based on the CVMP MRL summary report (EMEA/MRL/644/99 -FINAL) the candidate product is restricted exclusively to intravenous use for cattle and horses. Furosemide is rapidly eliminated following intravenous administration and clinically relevant accumulation during the proposed short treatment course (2 days) is not expected.

The withdrawal period on milk was established on the ADI (150 µg/person/day) as it is recommended by CVMP summary report. The available residue data demonstrate rapid

depletion of residues in milk, with theoretical consumer exposure remaining well below the established pharmacological ADI.

Maximum Residue Limits

Furosemide is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	**Marker residue**	**Animal Species**	**MRL**	**Target tissues**	**Other provision**	**Therapeutic Classification**
Furosemide	Not applicable	Bovine, Equide	No MRL required	Not Applicable	For intravenous administartion only	No entry

Withdrawal Periods

Based on the data provided above, withdrawal periods of 2 days for meat and offal in cattle and horses are justified. The product is not authorised for use in mares producing milk for human consumption. In cows producing milk for human consumption, a withdrawal period of 48 hours should be observed.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

A. Pre-Clinical Studies

No pre-clinical studies were performed.

Pharmacology

No pharmacological studies were performed.

Development of resistance and related risk in animals

Adequate warnings and precautions appear on the product literature.

Dose determination and confirmation

No dose determination and confirmation studies were performed.

Tolerance in the target species of animals

No tolerance studies in the target species were performed. The product literature accurately reflects the type and incidence of adverse effects which might be expected.

B. Clinical trials

No clinical trials were performed.

Absence of clinical trials was adequately justified.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

This section contains information on significant changes, which have been made after the original procedure, which are important for the quality, safety or efficacy of the VMP.

None.