College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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REFERENCE MEMBER STATE:
THE NETHERLANDS

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Laxasan 667 mg/ml syrup for dogs and cats

NL/V/0445/001/DC

PRODUCT SUMMARY

EU procedure number	NL/V/0445/001/DC
Name, strength and pharmaceutical form	Laxasan 667 mg/ml syrup for dogs and cats
Applicant	Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden The Netherlands
Active substance(s)	lactulose
ATCvet code	QA06AD11
Target species	Dogs, cats
Indication for use	For the treatment of constipation (e.g. due to intestinal atony after surgery, hairballs, massive intestinal contents). For the symptomatic treatment of disease conditions which require facilitated defecation (e.g. partial obstructions including those caused by tumours and fractures, rectal diverticulum, proctitis). Supportive treatment of poisoning in cases where facilitated defecation is beneficial.

PRODUCT INFORMATION

The 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)	Tractonorm Lax
Marketing authorisation holder	Pfizer Animal Health B.V.
MS where the RP is or has been authorised	NL
Marketing authorisation number EU procedure number	REG NL 3592
Date of authorisation	23 April 1992 (The reference VMP is not authorized anymore).
Date of completion of the original decentralised procedure	8 July 2026
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, NO, PL, PT, RO, SE, SI, SK, UK(NI)

*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

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, 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

A. Product description

The VMP contains lactulose, Liquid as the active substance. One strength is proposed: 667 mg/ml. No other ingredients are present in the VMP.

The veterinary medicinal product is a syrup, filled in 100 ml and 250 ml HDPE bottles, closed with a child-resistant polypropylene screw cap, and containing a LDPE syringe adapter. Polypropylene oral syringes of 5 mL and 10 ml are supplied in the package.

Lactulose, liquid is considered a self-preserving product and, hence, no additional preservative is needed.

The veterinary medicinal product is an established pharmaceutical form. Its formulation is developed to be qualitatively and quantitatively identical to the reference product Tractonorm Lax syrup for dogs and cats, REG NL 3592, Pfizer Animal Health B.V.

The development of the manufacturing process has been sufficiently described.

B. Description of the manufacturing method

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

Description on the manufacturing process VMP have been presented, which is a straightforward process of filtering the active substance (which is already provided in liquid state) and filling into the bottles. The manufacturing process is seen as a simple, standard process. IPCs for each manufacturing step are identified. The suitability of the filter used during the manufacture of the finished product is demonstrated.

Process validation data have been provided on two commercial batches of the proposed drug product. Furthermore, the applicant committed to validate a third commercial scaled batch.

C. Production and control of starting materials

The active substance is Lactulose, Liquid, an established active substance described in the European Pharmacopeia. The active substance is covered by a CEP and is manufactured in accordance with the principles of good manufacturing practice. The quality of water used in last steps of the manufacturing of the drug substance is specified (potable water).

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.

Sufficient information has been provided on the primary packaging material of the drug product as well as the co-packaged syringes. In addition, the information of the container used for the drug substance has been discussed by the applicant as this is not covered by the CEP.

The use of material of human or animal origin in the manufacture of the substance has been declared. Also, scientific data, including BSE/TSE statement and filled Table A, have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

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 are enclosed, and relevant parameters for the pharmaceutical form are considered in the drug product specification.

The specification limits have been set as per the European pharmacopeia.

An elemental impurities risk assessment is enclosed demonstrating the absence of detectable elemental impurities in the drug product.

The analytical methods used for identification, assay and related substances are the same as those described in the Ph. Eur monograph for Lactulose, Liquid.

The compendial method used for microbial quality has been specified and validated.

Batch analysis results on four batches of the drug product (two batches per filing size) are provided, confirming compliance with the proposed specification limits.

F. Stability tests

No re-test period is specified for the active substance in the CEP, and no re-test period has been granted. Instead, the drug substance will be tested prior to its use in the manufacture of the drug product in accordance with the drug substance specifications provided in Part C.1 of the dossier.

Stability data on two batches of the finished product, packed in HDPE bottles, have been provided, demonstrating the stability of the drug product up to 24 months when stored below 25 ºC in the upright position in the original primary and secondary packaging materials. Accordingly, 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 three months after first opening the immediate packaging is approved.

G. Other information

None.

3. SAFETY DOCUMENTATION (safety and residues tests)

The pharmacological and toxicological aspects of this VMP are identical to the reference VMP.

User Safety

The applicant has provided an user safety assessment in compliance with the relevant guideline which shows that this product is of low toxicity. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6, and lactulose is a well-known active substance which has been widely used for several decades in veterinary medicines and is a locally acting product, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

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. A Marketing Authorisation for the VMP in question is granted in view of the quality data presented and relevant commitments.

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.