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College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Laxatract 667 mg/ml syrup for dogs and cats

Created: January 2020

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0241/001/DC
Name, strength and pharmaceutical form	Laxatract 667 mg/ml syrup for dogs and cats
Applicant	Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel The Netherlands
Active substance(s)	Lactulose
ATC Vetcode	QA06AD11
Target species	Dogs and 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 due to for example tumours and fractures, rectal diverticulum, proctitis and poisoning).

MODULE 2

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The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	23 October 2018
Date 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, NO, PL, PT, RO, SE, SI, SK, UK

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.
The product 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 product was demonstrated according to the claims made in the SPC. The overall risk/benefit analysis is in favour of granting a marketing authorisation.

Laxatract is a generic application according to Article 13(1). The reference product is Tractonorm Lax of the company Pfizer Animal Health B.V., registered in The Netherlands under REG NL 3592 since 23 April 1992. Tractonorm Lax REG NL 3592 is also the product for data protection. The reference product is not authorized anymore.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains lactulose as lactulose, liquid (667 mg/ml), benzyl alcohol and purified water.

The container/closure system is an HDPE bottle in three different volumes containing 50 ml, 125 ml or 325 ml of the finished product. The bottles are closed with a syringe inlay closure (50 ml, and 125 ml) or a syringe inlay with a closure (325 ml). A 5 or 10 ml syringe is supplied with the product.

The choice of the formulation and the presence of the antimicrobial preservative is adequately justified.

The product is an established pharmaceutical form. Its development is not adequately justified.

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B. Method of Preparation of the Product

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

The product is manufactured using conventional manufacturing techniques.

Process validation data on two batches the product, filled in all three pack sizes have been presented in accordance with the relevant European guidelines. Validation on a third batch, and on full scale batches can be performed post registration.

C. Control of Starting Materials

The active substance is lactulose, liquid an established substance described in the European Pharmacopoeia. 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. For the manufacturing of the active substance reference is made to a Certificate of Suitability.

A copy of the Certificate of Suitability issued by the EDQM has 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 on intermediate products

Not applicable.

E. Control Tests on the Finished Product

The finished product specification is adequate for the control of the finished product both at release and during the stability studies.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data for two batches filled, in all tree pack sizes, from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has been provided for 15 batches, showing compliance with the specification throughout the proposed re-test period of 48 months. The absence of stability data of batches stored under the accelerated condition of 40°C/75%RH has been adequately justified. Furthermore, it has been demonstrated that water loss from the containers when stored under lower relative humidity is not significant.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product.

The efficacy of antimicrobial preservation has been demonstrated at the latest time-point available.

On the basis of the currently available data the claimed shelf-life of 24 months can be granted.

The claim of a 3 months stability after opening is based on the demonstration of stability for two batches broached and stored for three months mimicking the actual in-use situation (multiple withdrawals).

G. Other Information

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Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

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.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, 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 product are equivalent to those of the reference product.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product 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 product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

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The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Vetrinary Medicines Agencies website (www.HMA.eu).

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 product.

None.