

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Laxatract 667 mg/ml syrup for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substances:

Lactulose 667.0 mg
(as lactulose, liquid)

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)	2.0 mg
Water, purified	

Clear, viscous liquid, colourless or pale brownish-yellow.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

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).

3.3 Contraindications

Do not use in animals with total gastro-intestinal obstruction, digestive perforation or risk of digestive perforation.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Lactulose solution contains some free lactose and galactose, and may alter the insulin requirements in diabetic patients. Use with caution in animals with pre-existing fluid and electrolyte imbalances, since lactulose may exacerbate these conditions, if diarrhoea occurs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This veterinary medicinal product may cause flatulence and diarrhoea. Accidental ingestion should be avoided, especially by a child. To avoid accidental ingestion, the veterinary medicinal product must be used and kept out of reach of children. Always replace the cap after use.

This veterinary medicinal product contains benzyl alcohol. This preservative may cause hypersensitivity (allergic) reactions. People with known hypersensitivity to benzyl alcohol should avoid contact with the veterinary medicinal product. Wash hands after use. In case direct contact with skin or eyes should occur, rinse with clean water. If irritation persists, seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Common (1 to 10 animals / 100 animals treated):	Flatulence ^a , Gastric distension ^a , Abdominal cramp ^a
Very rare (<1 animal / 10.000 animals treated, including isolated reports):	Diarrhoea ^b
Undetermined frequency (cannot be estimated from the available data)	Dehydration ^b

^a Early in therapy, generally abate with time.

^b Signs of (relative) overdose, a veterinarian should be consulted.

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

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

Dogs and cats: 400 mg lactulose per kg bodyweight per day, corresponding to 0.6 ml veterinary medicinal product per kg body weight per day. This should preferably be divided into 2-3 doses over the day. The dosage may be adjusted as needed. To ensure a correct dosage, body weight should be determined as accurately as possible.

Approximately 2-3 days of treatment may be necessary before a treatment effect occurs. Contact a veterinarian to adjust the treatment if abdominal discomfort or diarrhoea occur. The veterinary medicinal product can be mixed with feed or given directly into the mouth.

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

An overdose does not cause other adverse effects than those stated in section 3.6. Replace fluids and electrolytes if necessary.

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

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QA06AD11

4.2 Pharmacodynamics

Lactulose is a disaccharide (galactose/fructose) that is not hydrolysable by mammalian gut enzymes. Upon reaching the colon, lactulose is metabolized by the resident bacteria resulting in the formation of low molecular weight acids (lactic, formic and acetic acid) and CO₂. These acids have a dual effect; they increase osmotic pressure drawing water into the bowel causing a laxative effect and also acidify colonic contents. The acidification causes NH₃ (ammonia) to migrate from the blood into the colon where it is trapped as [NH₄]⁺ (ammonium ion) and expelled with the faeces.

4.3 Pharmacokinetics

Lactulose is poorly absorbed after oral administration and it reaches the colon unchanged. In dogs and cats, less than 2% of an oral dose of lactulose is absorbed (in the small intestine). The absorbed drug is not metabolized and excreted unchanged in the urine within 24 hours.

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 of the immediate packaging: 3 months

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

50 ml and 125 ml: HDPE bottle closed with a (LDPE) syringe inlay and a (HDPE) cap.

325 ml: HDPE bottle closed with a (LDPE) syringe inlay and a cap (PP).
Oral syringe (5 and 10 ml): Polypropylene (PP) barrel and plunger, graduated per 0.2 ml.

Cardboard box of 1 bottle of 50 ml with a 5ml oral syringe
Cardboard box of 1 bottle of 125 ml with a 5ml oral syringe
Cardboard box of 1 bottle of 325 ml with a 10ml oral syringe

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22622/042/001

8. DATE OF FIRST AUTHORISATION

11/01/2019

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

24/09/2026

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).