SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Laxatract 667 mg/ml syrup for dogs and cats (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK, UK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains

Active substance:
Lactulose 667.0 mg
(as lactulose, liquid)

Excipient:
Benzyl alcohol (E1519) 2.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the 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).

4.3 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 the excipient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

Signs of flatulence, gastric distention, cramping, etc. are common early in therapy, but generally abate with time. Diarrhoea and dehydration are signs of (relative) overdose; if this occurs, a veterinarian should be consulted.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy and lactation

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration
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. 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

An overdose does not cause other adverse effects than those stated in section 4.6. Replace fluids and electrolytes if necessary.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Osmotically acting laxative, lactulose
ATCvet code: QA06AD11

5.1 Pharmacodynamic properties

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 CO_2. 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 NH_3 (ammonia) to migrate from the blood into the colon where it is trapped as $[NH_4]+$ (ammonium ion) and expelled with the faeces.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Water, purified

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening of the bottle: 3 months

6.4 Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 50406/4000

9. DATE OF FIRST AUTHORISATION

22 May 2019

10. DATE OF REVISION OF THE TEXT

May 2019

Approved: 22 May 2019