1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Laxasan 667 mg/ml syrup for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

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

Excipient:
None

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs, 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 including those caused by tumours and fractures, rectal diverticulum, proctitis).

Supportive treatment of poisoning in cases where facilitated defecation is beneficial.

3.3 Contraindications

Do not use in animals with gastrointestinal perforation or total gastrointestinal obstruction.
Do not use in animals at risk of gastrointestinal perforation.
Do not use in cases of hypersensitivity to the active substance.

3.4 Special warnings

In cases of persistent constipation, and particularly if repeated vomiting occurs, treatment must be discontinued and veterinary advice should be sought.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

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

The product may cause flatulence and diarrhoea. Avoid accidental ingestion, particularly by children. To avoid accidental ingestion, do not leave unattended filled syringe in the presence of children.

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, gastric distention, abdominal cramp[1]
Undetermined frequency (cannot be estimated from the available data)	Diarrhoea[2] Dehydration[2]

[1] early in therapy, these symptoms generally abate with time
[2] signs of (relative) overdose; a veterinarian should be consulted and administration of the product should be stopped.

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:
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known

3.9 Administration routes and dosage

Oral use.
To be administered at a total daily dose of 400 mg/kg body weight (corresponding to 0.6 ml/kg/day), preferably divided into 2-3 doses over 24 hours. Can be either mixed with food or administered directly into the mouth.
The dosage may be adjusted by the veterinarian based on the individual clinical response.
Approximately 2-3 days of treatment may be necessary before a treatment effect occurs.
Consult a veterinarian if abdominal discomfort or diarrhoea occur.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The syrup should be administrated using the provided 5 ml or 10 ml syringe. To obtain the required dose, remove the cap from the bottle and insert the syringe tip into the bottle adapter.
Invert the bottle to draw up the required dose. Do not remove the syringe while the bottle is in the inverted position.
Return the bottle to an upright position and remove the syringe from the bottle.

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

In cases of overdose, clinical signs are expected to be consistent with those listed 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.

Not applicable.

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 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.

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 the immediate packaging: 3 months.

5.3 Special precautions for storage

Do not store above 25 °C.
Keep the bottle in the original carton box to protect from light.
Store the bottle in an upright position.

5.4 Nature and composition of immediate packaging

100 ml or 250 ml white bottle (HDPE) closed with a syringe adapter inlay (LDPE) and a child-resistant screwcap (PP) in a cardboard box.
The veterinary medicinal product is supplied with 5 ml (graduated in 0.2 ml increments) and 10 ml (graduated in 0.5 ml increments) oral syringes (PP barrel /HDPE plunger).

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

Alfasan Nederland B.V.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10980/048/001

8. DATE OF FIRST AUTHORISATION

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

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*).