A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER AND THE IMMEDIATE PACKAGE

Cardboard box
HDPE bottles with fill volume: 125 ml and 325 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Laxatract 667 mg/ml syrup for dogs and cats
Lactulose

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains

Lactulose 667.0 mg
(as lactulose, liquid)

3. PHARMACEUTICAL FORM

Syrup

4. PACKAGE SIZE

50 ml
125 ml
325 ml
Oral syringe is enclosed.

5. TARGET SPECIES

Dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Shelf life after first opening of the bottle: 3 months
EXP .....
Once opened use by:

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50406/4000

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

HDPE bottle with fill volume: 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Laxatract 667 mg/ml syrup
lactulose

2. QUANTITY OF THE ACTIVE SUBSTANCE

Lactulose (as lactulose, liquid) 667.0 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE OF ADMINISTRATION

For oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Shelf life after first opening of the bottle: 3 months
EXP:
Once opened, use by….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Laxatract 667 mg/ml syrup for dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for the batch release:
Feramed.
Veemweg 1
3771 MT Barneveld
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Laxatract 667 mg/ml syrup for dogs and cats
lactulose

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 ml contains

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

Excipient:
Benzyl alcohol (E1519) 2.0 mg

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

4. INDICATIONS

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).

5. 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.

6. ADVERSE REACTIONS

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system *{national system details}*

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Shelf life after first opening of the bottle: 3 months
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and the carton after EXP.
The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

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.

Pregnancy and lactation
Can be used during pregnancy and lactation.

Overdose (symptoms, emergency procedures, antidotes)(if necessary)
An overdose does not cause other adverse effects than those stated in the section on adverse reactions. Replace fluids and electrolytes if necessary.

Interaction with other medicinal products and other forms of interaction
None known.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

Approved 03 May 2023