PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Urilin 40 mg/ml Syrup for dogs
Phenylpropanolamine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance: Phenylpropanolamine 40.29 mg
(equivalent to 50 mg phenylpropanolamine hydrochloride).

Excipients:
Sodium methyl parahydroxybenzoate (E219) 1.5 mg
Sodium propyl parahydroxybenzoate (E217) 0.15 mg

3. PHARMACEUTICAL FORM

Syrup, for oral administration.

4. PACKAGE SIZE

45 ml or 100 ml

5. TARGET SPECIES

Dogs (bitches)

6. INDICATION(S)

For use in dogs (bitches) to control urinary incontinence associated with acquired urethral sphincter incompetence.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {day/month/year}

Shelf life after first opening the immediate packaging: 3 months.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Keep the container in the outer carton.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

Always replace the cap firmly after use to ensure that the child resistant closure operates correctly.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited, Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, UK.

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

FURTHER INFORMATION

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Urilin 40 mg/ml Syrup for dogs
Phenylpropanolamine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:
Active substance: Phenylpropanolamine 40.29 mg
(equivalent to 50 mg phenylpropanolamine hydrochloride).

Excipients:
Sodium methyl parahydroxybenzoate (E219) 1.5 mg
Sodium propyl parahydroxybenzoate (E217) 0.15 mg

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

45 ml or 100 ml

4. ROUTE(S) OF ADMINISTRATION

For oral administration.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {day/month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

FURTHER INFORMATION

Do not store above 25°C.
Keep container in the outer carton.
Keep out of the reach and sight of children

To be supplied only on veterinary prescription.
Read the package leaflet before use.

Marketing authorisation holder: Dechra Limited, Dechra house, Jamage Industrial Estate, Stoke-on-Trent, Staffordshire, ST7 1XW, UK.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Urilin 40 mg/ml Syrup for dogs
Phenylpropanolamine

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

Marketing authorisation holder:
Dechra Limited, Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, UK.

Manufacturer for the batch release:
Dales Pharmaceuticals, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, UK.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Urilin 40 mg/ml Syrup for dogs
Phenylpropanolamine

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substance: Phenylpropanolamine 40.29 mg
(equivalent to 50 mg phenylpropanolamine hydrochloride).

Excipients:
Sodium methyl parahydroxybenzoate (E219) 1.5 mg
Sodium propyl parahydroxybenzoate (E217) 0.15 mg

4. INDICATION

Phenylpropanolamine is a sympathomimetic agent, which acts by direct stimulation of the smooth muscle of the urethral sphincter. It is indicated in the management of urinary incontinence associated with urethral sphincter incompetence in the bitch only.
The efficacy of phenylpropanolamine has only been demonstrated in ovariohysterectomised bitches.

5. CONTRAINDICATIONS

Do not use in animals treated with non-selective monoamine oxidase inhibitors.

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

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

In some dogs, loose stools, liquid diarrhoea, a decrease in appetite, arrhythmia and collapse have been reported following treatment with phenylpropanolamine in some dogs. Occasional nausea and vomiting have also been reported.
As phenylpropanolamine is a sympathomimetic drug it is possible to produce a wide range of effects, most of which mimic the results of excess stimulation of the sympathetic nervous system (e.g. effects on the heart rate and blood pressure).

Dizziness and restlessness have been reported in some dogs following treatment. Hypersensitivity may occur in very rare cases

7. TARGET SPECIES

Dogs (bitches)

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

For oral administration.
The recommended dose is 0.8 mg/kg body weight phenylpropanolamine (equivalent to 1mg/kg phenylpropanolamine HCL) three times daily in the feed, corresponding to 0.1 ml Urilin syrup/5 kg body weight three times daily.
1 drop for every 2.34 kg body weight three times daily in feed.

9. ADVICE ON CORRECT ADMINISTRATION

Do not shake the bottle, simply invert it over the food and count the required number of drops.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Keep out of the reach and sight of children.
Keep the container in the outer carton.
Shelf life after first opening the immediate packaging: 3 months.

Do not use after the expiry date stated on the label after EXP.

12. SPECIAL WARNINGS

For animal treatment only.

Because phenylpropanolamine is a sympathomimetic agent, it may affect the cardiovascular system, especially blood pressure and heart rate, and therefore should be used with caution in animals with cardiovascular diseases.
Care should be exercised in treating animals with severe renal or hepatic insufficiency, diabetes mellitus, hyperadrenocorticism, glaucoma or other metabolic disorders.
In bitches less than 1 year old the possibility of anatomical disorders contributing to incontinence should be considered prior to treatment.
It is not appropriate to use the product for the behavioural cause of inappropriate urination.

Special precautions for the person administering the veterinary medicinal product to animals

Phenylpropanolamine hydrochloride is toxic when overdoses are ingested. Adverse effects may include dizziness, headache, nausea, insomnia or restlessness, and increased blood pressure. High overdose may be fatal, especially in children.
In the event of accidental skin contact, wash the contaminated area with soap and water. Wash hands after use of the product.
In the event of accidental eye contact, rinse the eye with clean water for about 15 minutes and seek medical advice.
To avoid accidental ingestion the product must be used and kept out of the reach and sight of children.
Always replace the cap firmly after use to ensure that the child resistant closure operates correctly.
In the event of accidental ingestion, seek immediate medical attention showing the doctor the package leaflet.

Use during pregnancy, lactation or lay

Do not use in pregnant or lactating bitches.

Interaction with other medicinal products and other forms of interaction

Care should be exercised in administering the product with other sympathomimetic drugs, anticholinergic drugs, tricyclic antidepressants or specific type B monoamine oxidase.

Overdose

In healthy dogs, no side effects were observed at up to 5 times the recommended dose. However an overdose could produce signs of excessive stimulation of the sympathetic nervous system.

Treatment should be symptomatic. Alpha-adrenergic blockers may be appropriate in the case of severe overdose. However, no specific recommendation on drugs or dosages can be given.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

xx/xx/xxxx

15. OTHER INFORMATION

Urinary incontinence in the dog may be due to several underlying mechanisms.

Urilin is most effective in the control of urinary incontinence due to urethral sphincter incompetence in the bitch, particularly that associated with ovariohysterectomy.

Urilin is not effective in all cases and may be of limited effectiveness in other forms of urinary incontinence.

To be supplied only on veterinary prescription.

50 ml or 100 ml amber type III glass bottles containing 45 ml or 100 ml of syrup,with a low density polyethylene dropper and a polypropylene child resistant screw cap.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.