[Version 8, 10/2012]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Urilin 40 mg/ml syrup for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:	Phenylpropanolamine (equivalent to 50.0 mg phenylpropanolamine hydrochloride)	40.29 mg
Excipients:	Sodium methyl parahydroxybenzoate (E219)	1.5 mg
	Sodium propyl parahydroxybenzoate (E217)	0.15 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup.
Clear viscous solution.

4 CLINICAL PARTICULARS

4.1 Target species

Dogs (bitches).

4.2 Indications for use, specifying the target species

For the treatment of urinary incontinence associated with acquired urethral sphincter incompetence in the bitch only.
The efficacy of phenylpropanolamine has only been demonstrated in ovariohysterectomised bitches.

4.3 Contraindications

Please see section 4.7.
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.

4.4 Special warnings for each target species

It is not appropriate to use the product for the behavioural cause of inappropriate urination.

4.5 Special precautions for use

Special precautions for use in animals

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.

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

- People with known hypersensitivity to phenylpropanolamine should avoid contact with the veterinary medicinal product.
- 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.
- To avoid accidental ingestion the product must be used and kept out of the sight and reach 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.
- Contact with eyes and skin should be avoided.
- In the event of accidental skin contact, wash the contaminated area with soap and water. Wash hands after use of the product.
- Redness and irritation may develop after eye or skin contact with the product.
- In the event of accidental eye contact, rinse the eye with clean water for about 15 minutes and seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

In some dogs, loose stools, liquid diarrhoea, a decrease in appetite, arrhythmia and collapse have been reported following treatment with phenylpropanolamine. Occasional nausea and vomiting have also been reported. Treatment was continued depending on the severity of the undesirable effect observed.
As phenylpropanolamine is a sympathomimetic agent 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 were also occasionally reported.
Hypersensitivity may occur in very rare cases.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating bitches.

4.8 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.

4.9 Amount to be administered and administration route

For oral administration.
0.8 mg/kg body weight phenylpropanolamine (equivalent to 1 mg/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.

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

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Phenylpropanolamine hydrochloride is a sympathomimetic agent.
ATCvet Code: QG04BX91

5.1 Pharmacodynamic properties

Sympathetically innervated smooth muscles play a role in urethral closure, and both the α and β receptors are present. The α receptors play a role in urethral closure while β receptors innervate relaxation. The smooth muscle extends to the mid-urethra in females. The clinical effect of phenylpropanolamine is based on its stimulation effects on α-adrenergic receptors. This causes an increase in, and stabilisation of, the closure pressure in the urethra, which is innervated mainly by the adrenergic nerves.
Phenylpropanolamine is a racemic mixture of D and L enantiomers.

5.2 Pharmacokinetic particulars

In the dog, the mean half-life of phenylpropanolamine is approximately 3 hours with maximal plasma concentrations being found after approximately 4 hours. No accumulation of phenylpropanolamine has been observed after a dose of 1 mg/kg 3 times daily over 15 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium methyl parahydroxybenzoate (E219)
Sodium propyl parahydroxybenzoate (E217)
Maltitol liquid
Saccharin sodium
Citric acid monohydrate (E330)
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the container in the outer carton.

6.5 Nature and composition of immediate packaging

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.

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 product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

8 MARKETING AUTHORISATION NUMBERS

UK: Vm 10434/4003
IE: VPA 10799/018/001

9 DATE OF FIRST AUTHORISATION

Date of first authorisation:
UK - 28 January 2005
IE – 3 September 2010

Date of last renewal:
UK – 28 April 2015
IE – 10 July 2015

10 DATE OF ANY REVISION OF THE TEXT

27/08/2015