ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Incurin 1 mg tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Estriol 1 mg

Excipients:Qualitative composition of excipients and other constituents
Amylopectin
Potato starch
Magnesium stearate
Lactose

Round single-scored tablets.

3. CLINICAL INFORMATION

3.1 Target species

Dog (bitch).

3.2 Indications for use for each target species

The treatment of hormone-dependent urinary incontinence due to sphincter mechanism incompetence in ovariohysterectomised bitches.

3.3 Contraindications

Do not use in intact bitches, as the efficacy has only been established in ovariohysterectomised bitches.
Animals showing a polyuria-polydipsia should not be treated with veterinary medicinal product.
The use of veterinary medicinal product is contraindicated during pregnancy, lactation and in animals younger than 1 year.

3.4 Special warnings

High doses of oestrogen may have a tumour-promoting effect in target organs with oestrogen receptors (mammary glands).

3.5 Special precautions for use

Special precautions for safe use in the target species:

In case of oestrogenic effects, the dose should be lowered.

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dog (bitch):

Very common (>1 animal / 10 animals treated):	Swollen vulva[1,2], Mammary gland oedema[1,2]; Attractiveness to males[1,2]; Vomiting[1,2]
Rare (1 to 10 animals / 10,000 animaltreated):	Vaginal haemorrhage; Alopecia

[1] Observed at the highest recommended dose of 2 mg per dog.
[2] These effects are reversible after lowering the dose.

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 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

Do not use during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral use only.

A relationship between final effective dose and body weight has not been established and therefore the dose has to be determined for each dog on an individual basis.

The following dosing schedule is advised: start treatment with 1 tablet (1 mg estriol) every day. If treatment is successful, lower the dose to half a tablet a day. If treatment is not successful, increase the dose to 2 tablets a day to be given in one dose. Some dogs do not need daily treatment; treatment every other day may be tried, once the effective daily dose has been established.

The minimum dose given should not be less than 0.5 mg per dog per day. Ensure the dose used to achieve the therapeutic effect is as low as possible. Do not use more than 2 tablets per dog per day. If no response to treatment is obtained the diagnosis should be reconsidered in order to investigate other causes for the incontinence such as neurological disorders, bladder neoplasia, etc.

Animals should be re-examined every 6 months during treatment.

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

In case of overdose typical oestrogen effects may occur. These effects are reversible after lowering the dose.

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: QG03CA04

4.2 Pharmacodynamics

Estriol is a short-acting natural oestrogen. In ovarioectomised female dogs it has a beneficial effect on urinary incontinence. In the target animal safety study and the clinical trials, including long-term treatment, no signs of bone marrow suppression were observed. This is probably due to the short-acting oestrogenic character of estriol.

4.3 Pharmacokinetics

After oral administration Estriol is nearly completely absorbed from gastrointestinal tract. Nearly the whole Estriol is bound to Albumin in Plasma. Estriol is excreted in conjugated from via the urine. After oral administration of multiple doses no accumulation occurs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

5.3 Special precautions for storage

Do not store above 30 °C.

5.4 Nature and composition of immediate packaging

Blister package of clear PVC film backed by aluminium foil provided with heat seal coating (vinyl copolymer) on the side in contact with the tablets. One blister contains 30 tablets.

Pack size: carton box with 1 blister

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/018/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 24 March 2000

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

{DD month YYYY}

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Incurin 1 mg tablet

2. STATEMENT OF ACTIVE SUBSTANCES

Estriol 1 mg/tablet

3. PACKAGE SIZE

30 tablets.

4. TARGET SPECIES

Dog (bitch).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use only.

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V

14. MARKETING AUTHORISATION NUMBERS

EU/2/00/018/001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Incurin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Estriol 1 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Incurin 1 mg tablet

2. Composition

Each tablet contains:

Active substance:
Estriol 1 mg

Round single-scored tablets.

3. Target species

Dog (bitch).

4. Indications for use

This veterinary medicinal product is indicated for the treatment of hormone-dependent urinary incontinence due to sphincter mechanism incompetence in female dogs.

5. Contraindications

Do not use in intact bitches, as the efficacy has only been established in ovariohysterectomised bitches.
Animals showing a polyuria-polydipsia should not be treated with veterinary medicinal product.
The use of veterinary medicinal product is contraindicated during pregnancy, lactation and in animals younger than 1 year.

6. Special warnings

Special warnings:
High doses of oestrogen may have a tumour-promoting effect in target organs with oestrogen receptors (mammary glands).

Special precautions for safe use in the target species:
In case of oestrogenic effects, the dose should be lowered.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Pregnancy and lactation:

Do not use during pregnancy and lactation.

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

Overdose:
In case of overdose typical oestrogen effects may occur. These effects are reversible after lowering the dose.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
None known.

7. Adverse events

Dog (bitch):

Very common (>1 animal / 10 animals treated):
Swollen vulva[1,2], Mammary gland oedema[1,2]; Attractiveness to males[1,2]; Vomiting[1,2]
Rare (1 to 10 animals / 10,000 animals treated):
Vaginal haemorrhage; Alopecia

[1] Observed at the highest recommended dose of 2 mg per dog.
[2] These effects are reversible after lowering the dose.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

This veterinary medicinal product is intended for once daily oral administration.

Since there exists no relation between the final effective dose and the body weight, a fixed dose per kg body weight is not feasible. The dose has to be fixed for each dog on an individual basis. The following dosing schedule is advised: start treatment with 1 tablet every day. If treatment is successful lower the dose to half a tablet a day. If treatment is not successful increase the dose to 2 tablets a day. Some dogs do not need daily treatment; treatment every other day may be tried once the effective daily dose has been established.

9. Advice on correct administration

Not applicable.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/00/018/001

Pack size: carton box with 1 blister

15. Date on which the package leaflet was last revised

{DD month YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
Tel: + 37052196111

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: + 420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220