

## **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:**

For the full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Tablet

Round single-scored tablets.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dog (bitch).

#### **4.2 Indications for use, specifying the target species**

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

#### **4.3 Contraindications**

Do not use in intact bitches, as the efficacy has only been established in ovariectomised bitches.

Animals showing a polyuria-polydipsia should not be treated with Incurin.

The use of Incurin is contraindicated during pregnancy, lactation and in animals younger than 1 year.

#### **4.4 Special warnings for each target species**

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

#### 4.5 Special precautions for use

##### Special precautions for use in animals:

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.

##### Other precautions:

Not applicable.

#### 4.6 Adverse reactions (frequency and seriousness)

Dog (bitch):

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

<sup>1</sup>Observed at the highest recommended dose of 2 mg per dog.

<sup>2</sup>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 also section 16 of the package leaflet for contact details.

#### 4.7 Use during pregnancy, lactation or lay

Do not use (during the whole or part of the pregnancy).

The use is not recommended during lactation.

#### 4.8 Interaction with other medicinal products and other forms of interaction

None known.

#### **4.9 Amount(s) to be administered and administration route**

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.

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

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

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** estrogens,  
**ATCvet code:** QG03CA04

#### **5.1 Pharmacodynamic properties**

Estriol is a short-acting natural oestrogen. In ovariectomised 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.

#### **5.2 Pharmacokinetic particulars**

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 form via the urine.

After oral administration of multiple doses no accumulation occurs.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Amylopectin  
Potato starch  
Magnesium stearate  
Lactose

### **6.2 Major incompatibilities**

Not applicable

### **6.3 Shelf life**

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

### **6.4 Special precautions for storage**

Do not store above 30 °C.

### **6.5 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

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater

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**

MSD Animal Health UK Limited  
Walton Manor  
Walton  
Milton Keynes  
MK7 7AJ

**8. MARKETING AUTHORISATION NUMBER**

Vm 01708/5038

**9. DATE OF FIRST AUTHORISATION**

24 March 2000

**10. DATE OF REVISION OF THE TEXT**

April 2024

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT**

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on [www.gov.uk](http://www.gov.uk).

*Gavin Hall*

Approved: 01 December 2024