SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INCURIN 1 mg tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: estriol 1 mg/tablet

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Round single-scored tablets

4. CLINICAL PARTICULARS

4.1 Target species

Dogs (bitches).

4.2 Indications for use, specifying the target species

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

4.3 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 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.

4.6 Adverse reactions (frequency and seriousness)

Oestrogenic effects such as swollen vulva, swollen mammary glands and/or attractiveness to males and vomiting have been observed at the highest recommended dose of 2 mg per dog. The incidence is about 5-9 %. These effects are reversible after lowering the dose.
In rare cases vaginal bleeding occurred. In rare cases development of alopecia has also been observed.

4.7 Use during pregnancy, lactation or lay

Do not use this product during pregnancy or lactation. See also 4.3 Contraindications.

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 administration.
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 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.

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 from 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 Incompatibilities

None.

6.3 Shelf life

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

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
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5038

9. DATE OF FIRST AUTHORISATION

24 March 2000

10. DATE OF REVISION OF THE TEXT

March 2022

Approved 30 March 2022