

Incurin 1 mg tablets

Species:Dogs

Therapeutic indication:Pharmaceuticals: Hormones and therapeutically related products: Other sex hormones

Active ingredient:Estriol

Product:Incurin® 1 mg tablets

Product index:Incurin Tablets

Qualitative and quantitative composition

Active substance: estriol 1 mg/tablet.

See list of full excipients in section "Pharmaceutical particulars".

Pharmaceutical form

Round single-scored tablets.

Clinical particulars

Target species

Dogs (bitches).

Indications for use

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

Contra-indications

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.

Special warnings for each target species

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

Special precautions for use

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

Adverse reactions

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.

Use during pregnancy, lactation or lay

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

Interactions

None known.

Amounts 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.

Overdose

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

Withdrawal periods

Not applicable.

Pharmacological particulars

Pharmacotherapeutic group: estrogens, ATCvet code: QG03CA04.

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.

Pharmacokinetic properties

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.

Pharmaceutical particulars

Excipients

Amylopectin, Potato starch, Magnesium stearate and Lactose

Major incompatibilities

None.

Shelf life

3 years.

Special precautions for storage

Do not store above 30°C.

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.

Disposal

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Marketing Authorisation Holder (if different from distributor)

Intervet International BV, The Netherlands

Marketing Authorisation Number

EU/2/00/018/001.

Significant changes**Date of the first authorisation or date of renewal**

15 March 2000

Date of revision of the text

15 March 2010

Any other information

For animal treatment only. Keep out of the sight and reach of children.

Legal category

Legal category:POM-V

GTIN

GTIN description:Incurin 1mg 1x30tab:

GTIN:8713184156327

MSD Animal Health

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