B. PACKAGE INSERT

PACKAGE INSERT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Incurin 1 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Estriol, 1 mg per tablet

3. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER AND OF THE MANUFACTURING AUTHORIZATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

4. TARGET SPECIES

Dogs (bitches)

5. INDICATION(S)

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

6. DOSAGE FOR EACH SPECIES

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 initial 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Incurin is intended for oral administration, once daily or every other day.

8. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

9. CONTRA-INDICATIONS

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

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

10. UNDESIRABLE EFFECTS

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.

11. WITHDRAWAL PERIOD

Not applicable

12. SPECIAL STORAGE CONDITIONS, IF ANY

Do not store above 30 °C

13. SPECIAL WARNING(S), IF NECESSARY

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

14. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Any unused product or waste materials should be disposed of in accordance with local requirements.

15. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

16. OTHER INFORMATION

Estriol is a short-acting natural oestrogen. After oral administration of multiple doses no accumulation occurs. 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.

For any information about this veterinary product, please contact the local representative of the Marketing Authorisation Holder.

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