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
Estriol

2. STATEMENT OF ACTIVE AND OTHER SUBTANCES

Active substance: estriol 1 mg/tablet

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

Carton box with 1 blister. Each blister contains 30 tablets.

5. TARGET SPECIES

Dog.

6. INDICATION(S)

Treatment of hormone-dependent urinary incontinence due to sphincter mechanism incompetence in female dogs.

7. METHOD AND ROUTE OF ADMINISTRATION

For oral administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Not applicable.

10. EXPIRY DATE

Exp (Month / year)

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5038

17. MANUFACTURER'S BATCH NUMBER

Batch number.

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INCURIN 1 mg tablet.
Estriol

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

3. EXPIRY DATE

(Month / year)

4. BATCH NUMBER

Batch number.

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

INCURIN 1 mg tablet

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

Marketing authorisation holder and manufacturer responsible for batch release:
Intervet International B. V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

INCURIN 1 mg tablet
Estriol

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Active substance: estriol 1 mg/tablet

Round single-scored tablets.

4. INDICATION

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

6. ADVERSE REACTIONS

Mild, oestrogenic effects such as swollen vulva, swollen teats and/or attractiveness for males have been observed at the high dose of 2 mg. These effects are reversible after lowering the dose. Further, in some dogs, symptoms of nausea were observed. Because of its short-acting oestrogenic properties, Incurin does not induce bone marrow suppression in the dog.

In rare cases vaginal bleeding occurred. In rare cases development of alopecia has also been observed.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dog.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Incurin 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 PERIOD

Not applicable.

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.
Do not store above 30°C.
Do not use after the expiry date which is stated on the label after Exp.

12. SPECIAL WARNINGS

High doses of oestrogen may have a tumour-promoting effect in target organs with oestrogen receptors (mammary glands).
In case of overdose typical oestrogen effects may occur. These effects are reversible after lowering the dose.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

29/08/2014

15. OTHER INFORMATION

Each push-through strip contains 30 tablets. Each strip is packed in a carton box.

Oestriol is a short-acting natural oestrogen. In the incontinent female dog it has a beneficial effect on the urinary incontinence. Upon oral administration a steady state is reached after the second treatment day and no accumulation occurs after multiple dosing. Because of its short acting action, oestriol does not induce bone marrow suppression in the dog.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 30 March 2022