PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soloxine 0.5 mg Tablet

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance
Levothyroxine Sodium 0.50 mg

Excipients

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

5. TARGET SPECIES

Dogs

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

For the long term treatment of thyroid insufficiency in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral Use

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac S.A.

1ère avenue

2065m – L.I.D.

06516 Carros Cedex

France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4138

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soloxine 0.5 mg Tablet

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Virbac S.A.

3. EXPIRY DATE

4. BATCH NUMBER

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

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

Virbac S.A.,
Virbac 1,
1ère Avenue - 2065 M - LID,
BP 27, 06511 Carros Cedex,
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soloxine 0.3 mg Tablet

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

Active substance
Levothyroxine Sodium 0.50 mg

Excipients

4. INDICATION(S)

For the long term treatment of thyroid insufficiency in dogs.

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

Dogs

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

Oral Use

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not Applicable

11. SPECIAL STORAGE PRECAUTIONS

[Pharmaceuticals ONLY - *The following statement should be included if there is an in-use shelf life (example: solution for injection)]*

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

12. SPECIAL WARNING(S)

<User Warnings>

For Animal Treatment Only

13. SPECIAL 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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

[It is recommended that the following reference to the VMD Website is included:]

<Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.>

<15. OTHER INFORMATION>

[Distribution category]

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Approved: 04/09/2017