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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soloxine 0.1 mg Tablet

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:

Active substance
Levothyroxine sodium 0.10 mg

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

For the long term treatment of thyroid insufficiency in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

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

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 05653/4140

17. MANUFACTURER'S BATCH NUMBER

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Soloxine 0.1 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”

For animal treatment only

PACKAGE LEAFLET FOR:

Soloxine 0.1 mg Tablet
Levothyroxine sodium

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 0.1 mg Tablet

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

Each tablet contains:

Active substance
Levothyroxine sodium 0.10 mg

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

For oral administration.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

12. SPECIAL WARNING(S)

For Animal Treatment Only

Special warnings for each target species
None.

Special precautions for use in animals:

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

15. OTHER INFORMATION

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UK: Vm 05653/4140

Approved: 14/09/2017