

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Levothyroxine Sodium {Aspen}{Vale} 25 microgram tablets
Levothyroxine Sodium {Aspen}{Vale} 50 microgram tablets
Levothyroxine Sodium {Aspen}{Vale} 75 microgram tablets
Levothyroxine Sodium {Aspen}{Vale} 88 microgram tablets
Levothyroxine Sodium {Aspen}{Vale} 100 microgram tablets
Levothyroxine Sodium {Aspen}{Vale} 112 microgram tablets
Levothyroxine Sodium {Aspen}{Vale} 125 microgram tablets
Levothyroxine Sodium {Aspen}{Vale} 137 microgram tablets
Levothyroxine Sodium {Aspen}{Vale} 150 microgram tablets
Levothyroxine Sodium {Aspen}{Vale} 175 microgram tablets
Levothyroxine Sodium {Aspen}{Vale} 200 microgram tablets

Levothyroxine sodium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Levothyroxine sodium tablets contains 25 microgram, 50 microgram, 75 microgram, 88 microgram, 100 microgram, 112 microgram, 125 microgram, 137 microgram, 150 microgram, 175 microgram, 200 microgram of levothyroxine sodium respectively.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Tablets
28 tablets
50 tablets
60 tablets
84 tablets
90 tablets
100 tablets
112 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

Expiry Date: mm/yyyy

After opening the container the tablets should be used within 2 months.

9. SPECIAL STORAGE CONDITIONS

Levothyroxine sodium 25 and 125 micrograms

Store below 25°C

Levothyroxine sodium 50, 100 and 125 micrograms

Store below 30°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

{Name and Address}

<{tel}>

<{fax}>

<{e-mail}>

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

Lot: xxxxxx

14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Levothyroxine Sodium 25 microgram

Levothyroxine Sodium 50 microgram

Levothyroxine Sodium 75 microgram

Levothyroxine Sodium 88 microgram

Levothyroxine Sodium 100 microgram

Levothyroxine Sodium 112 microgram

Levothyroxine Sodium 125 microgram

Levothyroxine Sodium 137 microgram

Levothyroxine Sodium 150 microgram

Levothyroxine Sodium 175 microgram

Levothyroxine Sodium 200 microgram

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

Bottle

1. NAME OF THE MEDICINAL PRODUCT

Levothyroxine Sodium {Aspen}{Vale} 25 micrograms tablets
Levothyroxine Sodium {Aspen}{Vale} 50 micrograms tablets
Levothyroxine Sodium {Aspen}{Vale} 75 micrograms tablets
Levothyroxine Sodium {Aspen}{Vale} 88 micrograms tablets
Levothyroxine Sodium {Aspen}{Vale} 100 micrograms tablets
Levothyroxine Sodium {Aspen}{Vale} 112 micrograms tablets
Levothyroxine Sodium {Aspen}{Vale} 125 micrograms tablets
Levothyroxine Sodium {Aspen}{Vale} 137 micrograms tablets
Levothyroxine Sodium {Aspen}{Vale} 150 micrograms tablets
Levothyroxine Sodium {Aspen}{Vale} 175 micrograms tablets
Levothyroxine Sodium {Aspen}{Vale} 200 micrograms tablets

Levothyroxine sodium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Levothyroxine sodium tablets contains 25 micrograms, 50 micrograms, 75 micrograms, 88 micrograms, 100 micrograms, 112 micrograms, 125 micrograms, 137 micrograms, 150 micrograms, 175 micrograms, 200 micrograms of levothyroxine sodium respectively.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Tablets
28 tablets
50 tablets
60 tablets
84 tablets
90 tablets
100 tablets
112 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

Expiry Date: mm/yyyy

After opening the container the tablets should be used within 2 months.

9. SPECIAL STORAGE CONDITIONS

Levothyroxine sodium 25 and 125 micrograms

Store below 25°C

Levothyroxine sodium 50, 100 and 125 micrograms

Store below 30°C

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

12. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

13. BATCH NUMBER

Lot: xxxxxx

14. GENERAL CLASSIFICATION FOR SUPPLY

<[To be completed nationally]>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE