

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

NATURE/TYPE Outer packaging or Immediate packaging

Outer packaging.

1. NAME OF THE MEDICINAL PRODUCT

NOTEZINE 100 mg, scored tablets

Diethylcarbamazine citrate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Diethylcarbamazine citrate..... 196.4 mg
(equivalent to diethylcarbamazine 100.0 mg)

For one scored tablet

3. LIST OF EXCIPIENTS

Excipients with known effect: Wheat starch (gluten), lactose.

4. PHARMACEUTICAL FORM AND CONTENTS

Scored tablet, box of 20.

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

Not applicable.

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL PRECAUTIONS FOR STORAGE

No special storage conditions.

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

Not applicable.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder

SANOFI-AVENTIS FRANCE
1-13, BOULEVARD ROMAIN ROLLAND
75014 PARIS
FRANCE

Operating company

SANOFI-AVENTIS FRANCE
1-13, BOULEVARD ROMAIN ROLLAND
75014 PARIS
FRANCE

Manufacturer

Not applicable.

12. MARKETING AUTHORISATION NUMBER(S)

Authorised medicinal product no.:

13. BATCH NUMBER

Batch {number}

14. GENERAL CLASSIFICATION FOR PRESCRIPTION AND SUPPLY

Medicinal product not subject to medical prescription.

15. INSTRUCTIONS ON USE

This medicinal product is used in the treatment of:

- certain types of filariasis (infestation with *Wuchereria bancrofti*, *Brugia malayi*, *Brugia timori*),
- loiasis (infestation with *Loa loa*),
- and onchocerciasis (infestation with *Onchocerca volvulus*).

16. INFORMATION IN BRAILLE

As per current legislation.

PICTOGRAM TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

The pictogram must comply with the decree of 08 August 2008 in application of Article R. 5121-139 of the Public Health Code relating to the use of a pictogram on the outer packaging of certain medicines and products.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NATURE/TYPE Blisters/Strips

Blisters (PVC/Aluminium)

1. NAME OF THE MEDICINAL PRODUCT

NOTEZINE 100 mg, scored tablets

Diethylcarbamazine citrate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder

SANOFI-AVENTIS FRANCE

Operating company

SANOFI-AVENTIS FRANCE

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch {number}

5. OTHER

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NATURE/TYPE Small immediate packaging units

Not applicable.

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Not applicable.

2. METHOD OF ADMINISTRATION

Not applicable.

3. EXPIRY DATE

Not applicable.

4. BATCH NUMBER

Not applicable.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Not applicable.

6. OTHER

Not applicable.