

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

**CARTON FOR HDPE BOTTLE
LABEL FOR HDPE BOTTLE**

1. NAME OF THE MEDICINAL PRODUCT

Bupropion HCl Sandoz retard 150 mg, tabletten met gereguleerde afgifte
bupropion hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each modified-release tablet contains 150 mg of bupropion hydrochloride.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Modified-release tablets.

10 modified-release tablets
30 modified-release tablets
90 modified-release tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.
Swallow whole. Do not crush, chew or break.

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

Contains two pillows which should not be swallowed

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in the original package in order to protect from moisture and light.

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

Sandoz B.V., Hospitaaldreef 29, 1327 AH Almere

12. MARKETING AUTHORISATION NUMBER(S)

RVG 114395

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

17. UNIQUE IDENTIFIER – 2D BARCODE

Only for carton box:

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

Only for carton box:

PC {number}

SN {number}

NN {number}