

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Teva Lisinopril and hydrochlorothiazide 10 mg/12.5 mg Tablets

lisinopril and hydrochlorothiazide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 10 mg of lisinopril (as dihydrate) and 12.5 mg of hydrochlorothiazide.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Tablet

Calendar Pack
X Tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

oral use

Please read 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

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 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

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

<To be completed nationally>

15. INSTRUCTIONS ON USE

<To be completed nationally>

16. INFORMATION IN BRAILLE

<To be completed nationally>

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC:
SN:
NN:

THIS IS A REPRESENTATION OF AN ELECTRONIC RECORD THAT WAS SIGNED ELECTRONICALLY AND THIS PAGE IS THE MANIFESTATION OF THE ELECTRONIC SIGNATURE

Teva Pharmaceuticals Europe B.V

1.3.1 label-outer-10mg &12.5mg eu clean

APPROVALS

Signed by	Meaning of Signature	Server Date
Priya Mane	Regulatory Affairs Approval	02-May-2019 11:11:23 AM