1.3.1 Core Labelling

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Blister pack for 50 mg film-coated tablets
Blister pack for 200 mg film-coated tablets

1. NAME OF THE MEDICINAL PRODUCT

<[Product name] 50 mg film-coated tablets>
<[Product name] 200 mg film-coated tablets>

Voriconazole *(to be added to the labelling in case of a branded product name*)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 50 mg voriconazole.
Each tablet contains 200 mg voriconazole.

3. LIST OF EXCIPIENTS

Contains lactose monohydrate. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets

<50 mg><200 mg>
2 tablets
10 tablets
14 tablets
20 tablets
28 tablets
30 tablets
50 tablets
56 tablets
100 tablets
30 x 1 tablets (unit dose)
100 x 1 tablets (unit dose)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral 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.: {mm/yyyy}

9. SPECIAL STORAGE CONDITIONS

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 {number}

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

<2D barcode carrying the unique identifier included.> [to be added to the Labelling only in case implemented]

18 UNIQUE IDENTIFIER – HUMAN READABLE DATA

< PC: {number}
SN: {number}
NN: {number}>
[to be added to the Labelling only in case implemented]