PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Relenza 5 mg/dose, inhalation powder, pre-dispensed.

Zanamivir

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each blister contains zanamivir 5 mg.

3. LIST OF EXCIPIENTS

Lactose monohydrate (which contains milk proteins)

4. PHARMACEUTICAL FORM AND CONTENTS

Inhalation powder, pre-dispensed

1 Diskhaler

5 Rotadisks (4 blisters per Rotadisk)

1 Rotadisk (4 blisters)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Inhalation 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

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC

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

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

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:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

ROTADISK TUB

1. NAME OF THE MEDICINAL PRODUCT

Relenza 5 mg/dose, inhalation powder, pre-dispensed.

Zanamivir

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each blister contains zanamivir 5 mg.

3. LIST OF EXCIPIENTS

Lactose monohydrate (which contains milk proteins)

4. PHARMACEUTICAL FORM AND CONTENTS

Inhalation powder, pre-dispensed

5 Rotadisks (4 blisters per Rotadisk)

1 Rotadisk (4 blisters)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Inhalation 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

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC

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

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

<[To be completed nationally]>

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

ROTADISK

1. NAME OF THE MEDICINAL PRODUCT

Relenza 5 mg (x4)

zanamivir

Rotadisk

2. NAME OF THE MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

3. EXPIRY DATE

EXP

4. BATCH NUMBER

LOT

5. OTHER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

DISKHALER LABEL

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

RELENZA

Diskhaler

GlaxoSmithKline

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

4. BATCH NUMBER

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER