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 30°C

| 10. | SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS |
|------------|---|
| OR | WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF |
| AP | PROPRIATE |

| 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

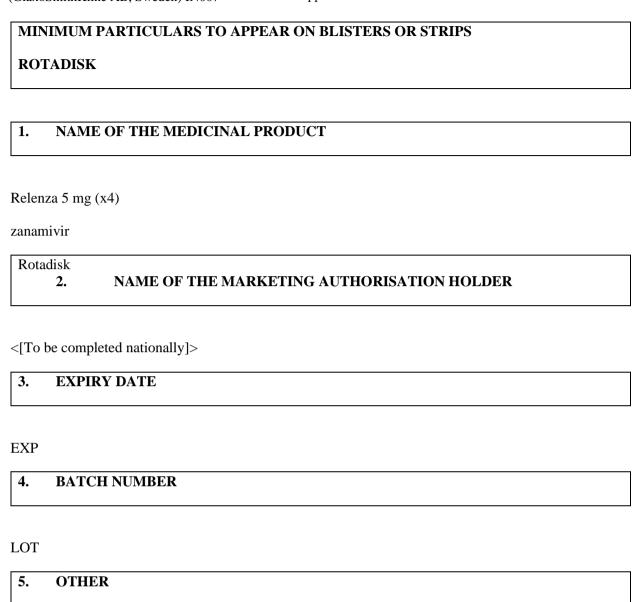
EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 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 |
| LOT | |
| 14. | GENERAL CLASSIFICATION FOR SUPPLY |
| Medic | cinal 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 SMALL IMMEDIATE PACKAGING UNITS DISKHALER LABEL

| 1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION | | |
|---|--|--|
| | | |
| RELENZA | | |
| Diskhaler | | |
| Diskilalei | | |
| GlaxoSmithKline | | |
| | | |
| 2. METHOD OF ADMINISTRATION | | |
| | | |
| | | |
| 2 EVDIDY DATE | | |
| 3. EXPIRY DATE | | |
| | | |
| | | |
| 4. BATCH NUMBER | | |
| | | |
| | | |
| | | |
| 5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT | | |
| | | |
| | | |
| 6. OTHER | | |
| | | |