# 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

May 2025

#### 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 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

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**

May 2025

### 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

#### Zanamivir Powder for Inhalation 5mg/dose (GlaxoSmithKline AB, Sweden) IN007

#### WHOPAR part 5 Suppliers submission

#### May 2025

(1) What is in this leaflet	- ,	2 What you need to know before you use Relenza		3 How to use Relenza	If there is a flu outoreak in your local community: • Adults and collions (aged 5 years or more): the recommended does is 2 inhalations (2 blisten)	Swearing, sometimes of the face, mouth or throat, Causing difficulty in preathing. Compse.
<ul> <li>4 Wat National S and Watt Nationa</li></ul>	- If you are asymptic asymptic or any of the interaction (3) into marking (4) and	<ul> <li>your ooctor for advice before taking this modifie.</li> <li>There is only limited information about the safety of Relenza for pregnant women. Although there a no evidence so far that Relenza harma unborn bables, you should not use, it during pregnancy</li> </ul>	Driving and using machines. Reters about on a friest your about to drive or an machine. Recense contains lactore and milk protein Regenerations and the second second second second regeneration. Hypo have been totic by your doctor that you have a resolution to your doctor that you have before taking the medicinal product.	Array use this medicine stactly a your accord of planticidit stack large to b. b.a. planticidit stack large to b. b.a. Before a spacetest making, which you inhate the stack of the s	once a tay for up to 28 day. <b>Hy ou see more Release than you should</b> Hy one see more Release than you should Hy one see more Release than you should Hy one segment of the see more release <b>Hy our long to and finance</b> , then see that hy one long to and finance, then see you and hy one long to and finance, then see you and hy one long to and finance, then see you and hy one long to and finance, then see you and hy one long to and finance, then see you and hy one long to and finance, then see you and hy one long to and finance, then see you and hy one long to and finance, then see you hy one long to and finance, then see you hy one long to an expective of the sec Hy one long to any set of the sec Hy one long to any set of the sec Hy sec the sec of the sec Hy sec of the sec of the sec of the sec Hy sec of the sec of the sec of the sec Hy sec of the sec of the sec of the sec Hy sec of th	If you get any of these spreatments • Contact you could in ministerious, • Contact you could in ministerious, <b>Section 2014</b> (1997) <b>Denn</b> side affects are used any spliter too <b>Denn</b> side affects are used any spliter too mapped formula del system summariants of the paper any spliter that delives you summariants of the paper any spliter that delives the summariant of the paper any spliter that delives the summariant of the spliter any spliter that delives the summariant of the spliter any spliter that the spliter of the spliter of the spliter of the summariant of the spliter of the spliter of the summariant of the spliter of the <b>Deliver uncommon side effects</b> <b>Desn</b> spliter that <b>Dis 11</b> ht Dispersion with Belancer. There solves that <b>Dis 11</b> ht Dispersion with Belancer. There is any split the spliter of the summariant <b>Deliver uncommon side effects</b> Head of the sum of the sum spliter of the spliters of the sum spliters of the summariant <b>Deliver uncommon side effects</b> Head of the spliter of the sum of the spliters of the spliters of the spliter of the sum of the spliters of the spliters of the spliter of the sum of the spliters of the split

# If you get any of these effects: Stop using Reenza and get medica nep Immediatory. Contact your doctor or the nearest hospital emergency department.

#### Sudden changes in behaviour, hallucinations and fits

hallucinations and fHs During treatment with Rulesac, changes in behavious such as conflation and unresponsiveling have an observing survively or hereing with the second second bearing survively or hereing with the second second unresponsible to the second second second second parents should be uppeaking service to watch and the fit was any atom herein bear second second second key second second second second second hereing second second second second second the second second second second second hereing second second second second second hereing second second second second hereing second s If you get any of these symptoms: Gontact your doctor immediately.

#### Reporting of side effects

Hopevering of side effects, tait to your doctor or pharmacit. The includes any possible side effects not initial in this leaffet. You can also report side effects directly via HIPA Pharmacovigiance. Leaffect Terrace, IBL - Dublin 2; Tet: +353 1 6764971; Far: +353 1 676517. Autom 2; 167: 433 1 Growshi; material 433 1 Group to: www.honais: E-mait.methofshiftpma.is sorting add ethicits you can help provide more nation on the safety of the medicine.

#### 5 How to store Relenza

Keep this medicine out of the sight and reach of

heldbarn Do not use folger or the Datheet after the script date (DBV) which is stated on the pack. Do not stress feature adows and the stress stress or household wate. And your pareacitines wis wetterwater or household wate. And your pareacitines wis assures with help projects the survivonment. As your phramical how to the wave away the Biblisher you no longer use. These measures with help profile survivonment.

#### 6 Contents of the pack and other information

#### What Relenza contains The active substance is zanamivir (5 mg per dose) The other ingredient is lactose monohydrate (which contains milk protein)

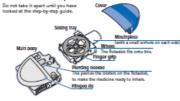
What Relenza looks like and contents of What Relenza looks like and contents of the pack Relenza powder is contained in the four bitters on the alver-coloured unminum folds, called a Rotadisk, Each bitter contains 5 mg of zaramen. The medicine is tabled through the model from the Rotadisk uning a platic device called a Dishafate. Relatized is upged in two types of pack = a 1-digy staffat pack containing one Relenza Rotadisk and on Dishafate

 a 5-day braitment pack containing five Relenza Rotadaka and one Diskhaler Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Hower: GlassSmithKins (Ireland) Ltd., 12 Riverwalk, Citywert Business Campus, Dublin 24, Ireland Manufacturer: Glaso Wellcome Production, Zone Industrielle No.2, 23 Rue Lavonier, 27000 Evreux, France Manutacturer for Disknaser. GlassSmithKine Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24,

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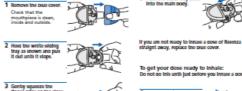
#### The Rotadisk fits into the Diskhaler

#### The Rotadisk fits onto the wheel of the 69 Diskhaler.

The Diskhaler has three parts:

#### en Taylor Australia Attica (00) The Rotadisk contains four blisters. Each blister contains 5 mg of zanamivir. A dose is normally two blisters (10 mg). important: • Do not plence any of the blisters on the Rotadisk before you load it onto

the Diskhaler. <sup>1</sup> You can keep a Rotadisk on the Diskhaler between does, but 00 Rot plena a bolker until just bolkey you innaw your oose. 16 Gog the Diskhaler coan. Wepe the mouthproce with a finue after you 17 Kay your dock or parametelt of any martinetion or processors with the Disknawe and Rotadist.



Step-by-step guide to using your Relenza Diskhaler



To load a Rotadisk into the Diskhaler:

1 Remove the plue cover.

Check that the

#### 4 Prace a new Reienza Rotaolsk on the whee Make sure the printed U side is up, with the blisters facing downwards.

The blisters fit into the holes in the wheel.



5 Push the write tray pack

into the main poor



#### Keep the Diskha Pusn the ild back down.

Your Diskhaler is now ready for use. Keep it horizontal until you have inhaled your dose.

If you use other Innaied medication, make sure you read 'Using Refenza with inhaled medication for breathing problems' in Section 2 of this leaflet.

SCHERON SCHEROL

To inhale the medication: 7 Do not put the Disknave into your mouth yet. Breathe out as far as is comfortable, keeping the Diskhaier away from your mouth. Do not powe into the Disknave. If you do, you will blow the powder out of the Rotadisk.



#### airholes on the side of the mouthpiece. Take one quick, ocep proatn in through the mouthpiece. Hold this breath for a few seco Keep th on de Remove the Disknater from your mouth. Carry on notaing your preath for a few more seconds

or as long as is comfortable To prepare the next blister (the second part of your dose

B put the while tray out a star as it while go ide not remove it completely), then put it back in again. This will turn the wheel so the next bifater will appe Repeat if necessary until a full bifate is positioned under the piering needs. Repeat tapp 6 and 7 to inhale the moditine.

### 9 After you have inhaled the full dose (normally two blisters)

When the mouthplece with a thsue and replace the plue cover. It is important to keep the Diskhaler clean. To replace the Rotadisk:

10 When all four blisters are empty, remove the Rotadiak from the Diskhaler and insert a new one, using steps 1 to 5.