

1 **Patient Information About:**

2 **RELENZA[®]**
3 **(zanamivir for inhalation)**
4

5 This leaflet contains important patient information about RELENZA (zanamivir for inhalation), and
6 should be read completely before beginning treatment. It does not, however, take the place of
7 discussions with your health care provider about your medical condition or your treatment. This
8 summary does not list all benefits and risks of RELENZA. The medication described here can only
9 be prescribed and dispensed by a licensed health care provider, who has information about your
10 medical condition and more information about the drug, including how to take it, what to expect, and
11 potential side effects. If you have any questions about RELENZA, talk with your health care provider.

12

13 **What is RELENZA?**

14 RELENZA (ruh-LENS-uh) is a medicine to treat influenza (flu, infection caused by influenza virus). It
15 belongs to a group of medicines called neuraminidase inhibitors. These medications attack the
16 influenza virus and prevent it from spreading inside your body. RELENZA treats the cause of
17 influenza at its source, rather than simply masking the symptoms.

18

19 **Important Safety Information About RELENZA**

20 Some patients have had bronchospasm (wheezing) or serious breathing problems when they used
21 RELENZA. Many but not all of these patients had previous asthma or chronic obstructive pulmonary
22 disease. RELENZA has not been shown to shorten the duration of influenza in people with these
23 diseases. Because of the risk of side effects and because it has not been shown to help them,
24 RELENZA is not generally recommended for people with chronic respiratory disease such as asthma
25 or chronic obstructive pulmonary disease.

26 If you develop worsening respiratory symptoms such as wheezing or shortness of breath, stop
27 using RELENZA and contact your health care provider right away.

28 If you have chronic respiratory disease such as asthma and chronic obstructive pulmonary
29 disease and your health care provider has prescribed RELENZA, you should have a fast-acting,
30 inhaled bronchodilator available for your use. If you are scheduled to use an inhaled bronchodilator
31 at the same time as RELENZA, use the inhaled bronchodilator **before** using RELENZA.

32 Read the rest of this leaflet for more information about side effects and risks.

33 Other kinds of infections can appear like influenza or occur along with influenza, and need
34 different kinds of treatment. Contact your health care provider if you feel worse or develop new
35 symptoms during or after treatment, or if your influenza symptoms do not start to get better.

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36 **Who should not take RELENZA?**

37 RELENZA is not generally recommended for people who have chronic lung disease such as asthma
38 or chronic obstructive pulmonary disease. RELENZA has not been shown to shorten the duration of
39 influenza in people with these diseases, and some people have had serious side effects of
40 bronchospasm and worsening lung function. (See the section of this Patient Information entitled
41 **“Important Safety Information About RELENZA.”**)

42 You should not take RELENZA if you are allergic to zanamivir or any other ingredient of
43 RELENZA. Also tell your health care provider if you have any type of chronic condition including lung
44 or heart disease, or if you are pregnant.

45

46 **Who should consider taking RELENZA?**

47 Adult and pediatric patients at least 7 years of age who have influenza symptoms that appeared
48 within the previous day or two. Typical symptoms of influenza include sudden onset of fever, cough,
49 headache, fatigue, muscular weakness, and sore throat.

50

51 **What can I expect if I take RELENZA?**

52 In clinical studies, adults and children with influenza who took RELENZA recovered approximately
53 one day faster on the average than influenza patients who did not take RELENZA. RELENZA does
54 not treat flu-like illness that is not caused by influenza virus.

55

56 **Can I take other medications with RELENZA?**

57 RELENZA has been shown to have an acceptable safety profile when used as labeled, with minimal
58 risk of drug interactions. Your health care provider may recommend taking other medications,
59 including over-the-counter medications, to reduce fever or other symptoms while you are taking
60 RELENZA. Before starting treatment, make sure that your health care provider knows if you are
61 taking other medicines. If you are scheduled to use an inhaled bronchodilator at the same time as
62 RELENZA, you should use the inhaled bronchodilator **before** using RELENZA.

63

64 **How and when should I take RELENZA?**

65 RELENZA is packaged in medicine disks called ROTADISKS[®] and is inhaled by mouth using a
66 delivery device called a DISKHALER[®]. Each ROTADISK contains 4 blisters. Each blister contains
67 5 mg of active drug and 20 mg of lactose powder.

68 You should receive a demonstration on how to use RELENZA in the DISKHALER from a health
69 care provider. Before taking RELENZA, read the “Patient Instructions for Use”. Make sure that you
70 understand these instructions and talk to your health care provider if you have any questions.
71 Children who use RELENZA should always be supervised by an adult who understands how to use
72 RELENZA. Proper use of the DISKHALER to inhale the drug is necessary for safe and effective use
73 of RELENZA.

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74 The usual dose is 2 inhalations of RELENZA (1 blister per inhalation) twice daily (in the morning
75 and evening) for 5 days. It is important that you begin your treatment with RELENZA as soon as
76 possible from the first appearance of your flu symptoms. Take 2 doses on the first day of treatment
77 whenever possible if there are at least 2 hours between doses. Never share RELENZA with anyone,
78 even if they have the same symptoms. If you feel worse or develop new symptoms during treatment
79 with RELENZA, or if your flu symptoms do not start to get better, stop using the medicine and
80 contact your health care provider.

81

82 **What if I miss a dose?**

83 If you forget to take your medicine at any time, take the missed dose as soon as you remember,
84 except if it is near the next dose (within 2 hours). Then continue to take RELENZA at the usual times.
85 You do not need to take a double dose. If you have missed several doses, inform your health care
86 provider and follow the advice given to you.

87

88 **What are important or common possible side effects of treatment with RELENZA?**

89 Some patients have had breathing problems while taking RELENZA. This can be very serious and
90 need treatment right away. Most of the patients who had this problem had asthma or chronic
91 obstructive pulmonary disease, but some did not. If you have trouble breathing or have wheezing
92 after your dose of RELENZA, stop taking RELENZA and get medical attention.

93 In studies, the most common side effects during treatment with RELENZA in adults and
94 adolescents have been headaches; diarrhea; nausea; vomiting; nasal irritation; bronchitis; cough;
95 sinusitis; ear, nose, and throat infections; and dizziness. In children, the most common side effects
96 were ear, nose, and throat infections; vomiting; and diarrhea. Other side effects that have been
97 reported, but were not as common, include allergic reactions and rashes.

98 This list of side effects is not complete. Your health care provider or pharmacist can discuss with
99 you a more complete list of possible side effects with RELENZA. Talk to your health care provider
100 promptly about any side effects you have.

101 Please refer to the section entitled "**Important Safety Information about RELENZA**" for
102 additional information.

103

104 **Should I get a flu shot?**

105 RELENZA has not been shown to keep people from getting influenza and is not a substitute for a flu
106 shot. You should receive an annual flu shot according to guidelines on immunization practices that
107 your health care provider can share with you.

108

109 **What if I am pregnant or nursing?**

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110 If you are pregnant or planning to become pregnant while taking RELENZA, talk to your health care
111 provider before taking this medication. RELENZA is normally not recommended for use during
112 pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown.

113

114 **How and where should I store RELENZA?**

115 RELENZA should be stored at room temperature below 77°F (25°C). RELENZA is not in a childproof
116 container. Keep RELENZA out of the reach of children. Discard the DISKHALER after finishing your
117 treatment.

118

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122 Research Triangle Park, NC 27709

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RELENZA[®]
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Patient Instructions for Use
RELENZA[®]
(ZANAMIVIR FOR INHALATION)

**IMPORTANT: Read Step-by-Step Instructions
before using the DISKHALER[®].**

Be sure to take the dose your health care provider has prescribed.

BEFORE YOU START:

Please read the entire Patient Information for important information about the effects of RELENZA including the section “Important Safety Information about RELENZA” for information about the risk of breathing difficulties.

If RELENZA is prescribed for a child, dosing should be supervised by an adult who understands how to use RELENZA and has been instructed in its use by a health care provider.

Parts of the DISKHALER:

Step-by-step instructions for using the DISKHALER[®].

Step A: Load the medicine into the DISKHALER

1. Start by pulling off the blue cover.
2. **Always check inside the mouthpiece to make sure it is clear before each use. If foreign objects are in the mouthpiece, they could be inhaled and cause serious harm.**
3. Pull the white mouthpiece by the edges to extend the white tray all the way.
4. Once the white tray is extended all the way, find the raised ridges on each side of it. Press in these ridges, both sides at the same time, and **pull the whole white tray out of the DISKHALER body.**
5. Place one silver medicine disk onto the dark brown wheel, flat side up. The four silver blisters on the underside of the medicine disk will drop neatly into the four holes in the wheel.
6. Push in the white tray as far as it will go. Now the DISKHALER is loaded with medicine.

Step B: Puncture the blister

Be sure to keep the DISKHALER level.

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173 **The DISKHALER punctures one blister of medicine at a time so you can inhale the right**
174 **amount. It does not matter which blister you start with. Check to make sure that the silver foil**
175 **is unbroken.**

176

- 177 1. **Be sure to keep the DISKHALER level so the medicine does not spill out.**
- 178
- 179 2. Locate the half-circle flap with the name "RELENZA" on top of the DISKHALER.
- 180
- 181 3. Lift this flap from the outer edge until it cannot go any farther. Flap must be **straight up** for the
- 182 plastic needle to puncture both the **top** and **bottom** of the silver medicine disk inside.
- 183
- 184 4. Keeping the DISKHALER level, click the flap down into place.
- 185

186

187

Step C: Inhale

188

- 189 1. Before putting the white mouthpiece into your mouth, breathe all the way out (exhale).

190

191 **Then put the white mouthpiece into your mouth. Be sure to keep the DISKHALER level so the**
192 **medicine does not spill out.**

193

- 194 2. Close your lips firmly around the mouthpiece. Be sure not to cover the small holes on either side
- 195 of it.
- 196
- 197 3. Breathe in through your mouth steadily and as deeply as you can. Your breath pulls the
- 198 medicine into your airways and lungs.
- 199
- 200 4. Hold your breath for a few seconds to help RELENZA stay in your lungs where it can work.

201

202 **To take another inhalation, move to the next blister by following Step D below.**

203

204 **Once you've inhaled the number of blisters prescribed by your health care provider, replace**
205 **the cover until your next dose.**

206

207

Step D: Move the medicine disk to the next blister

208

209

- 210 1. **Pull** the mouthpiece to extend the white tray, without removing it.
- 211
- 212 2. Then **push** it back until it clicks. This pull-push motion rotates the medicine disk to the next
- 213 blister.
- 214
- 215 3. To take your next inhalation, repeat Steps B and C.

216

217 **If all four blisters in the medicine disk have been used, you are ready to start a new medicine**
218 **disk (see Step A). Check to make sure that the silver foil is unbroken each time you are ready**
219 **to puncture the next blister.**

220

IMPORTANT INSTRUCTIONS
<ul style="list-style-type: none">▪ Read this entire leaflet before using RELENZA. Even if you have had a previous prescription for RELENZA, read this leaflet to see if any information has changed.▪ The usual dose is 2 inhalations. However, you must take the number of inhalations your health care provider has prescribed.▪ If you feel worse or develop new symptoms during or after treatment, or if your flu symptoms do not start to improve, stop using the medicine and contact your health care provider.

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- Keep out of reach of children.
- Always check inside the mouthpiece to make sure it is clear before each use. If foreign objects are in the mouthpiece, they could be inhaled and cause serious harm.
- Always replace the cover after each use.
- Throw away the DISKHALER after treatment is completed.
- This DISKHALER is for use only with RELENZA. Do not use the RELENZA DISKHALER device with FLOVENT[®] (fluticasone propionate) and do not use RELENZA with the FLOVENT DISKHALER device.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) (see USP Controlled Room Temperature).

REMEMBER: This medicine has been prescribed for you by your health care provider.
DO NOT give this medicine to anyone else.

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