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## Rezira

Generic name: hydrocodone and pseudoephedrine

Drug class: Upper respiratory combinations

Approval date: June 8, 2011

**Company:** Cypress Pharmaceutical, Inc. **Treatment for:** Cough and Nasal Congestion

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Uses Before taking Dosage Warnings Side effects Overdose

# **FDA Approves Rezira**

The U.S. Food and Drug Administration (FDA) has approved a new drug application (NDA) for Rezira (hydrocodone bitartrate and pseudoephedrine hydrochloride) Oral Solution (CIII) for the relief of cough and symptoms associated with the common cold.

### What is Rezira used for?

Rezira is used for:

• Relieving congestion and cough due to colds, flu, or hay fever. It may also be used for other conditions as determined by your doctor.

## What is Rezira?

Rezira is a decongestant and cough suppressant combination. It works by constricting blood vessels and reducing swelling in the nasal passages. This allows you to breathe more easily. The cough suppressant works in the brain to decrease the cough reflex to help decrease a dry cough.

### Do NOT use Rezira if:

- you are allergic to any ingredient in Rezira or any other codeine or morphine related medicine (eg, codeine, oxycodone).
- you have severe high blood pressure, rapid heartbeat, or other severe heart problems (eg, heart blood vessel disease)
- you take sodium oxybate (GHB) or if you have taken furazolidone or a monoamine oxidase (MAO) inhibitor (eg, phenelzine) within the last 14 days

Contact your doctor or health care provider right away if any of these apply to you.

# Before using Rezira:

Some medical conditions may interact with Rezira. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

- if you are pregnant, planning to become pregnant, or are breast-feeding
- if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
- if you have allergies to medicines, foods, or other substances
- if you have an abnormal heartbeat or other heart problems
- if you have a history of adrenal gland problems (eg, tumor), high blood pressure, diabetes, heart blood vessel problems, stroke, glaucoma, seizures or epilepsy, or an overactive thyroid
- if you have or recently have had any head or brain injury, brain tumor, increased pressure in the brain, or infection of the brain or nervous system
- if you have a history of any lung or breathing problems, asthma, stomach problems, bowel problems (eg, chronic inflammation or ulceration of the bowel), gallbladder problems (eg, gallstones), an enlarged prostate gland or other prostate problems, or you have had recent abdominal surgery
- if you have a history of alcohol or substance abuse or suicidal thoughts or behavior

Some MEDICINES MAY INTERACT with Rezira. Tell your health care provider if you are taking any other medicines, especially any of the following:

- Naltrexone because it may decrease Rezira's effectiveness
- Beta-blockers (eg, propranolol), catechol-O-methyltransferase (COMT) inhibitors (eg, tolcapone), furazolidone, indomethacin, MAO inhibitors (eg, phenelzine), or tricyclic antidepressants (eg, amitriptyline) because they may increase the risk of Rezira's side effects
- Cimetidine and sodium oxybate (GHB) because the risk of severe drowsiness, breathing problems, and seizures may be increased
- Digoxin and droxidopa because the risk of irregular heartbeat or heart attack may be increased
- Bromocriptine because the risk of its side effects may be increased by Rezira
- Guanadrel, guanethidine, mecamylamine, methyldopa, or reserpine because their effectiveness may be decreased by Rezira

This may not be a complete list of all interactions that may occur. Ask your health care provider if Rezira may interact with other medicines that you take. Check with your health care provider before you start, stop, or change the dose of any medicine.

Rezira pregnancy and breastfeeding warnings (more detail)

# How to use Rezira:

Use Rezira as directed by your doctor. Check the label on the medicine for exact dosing instructions.

- Take Rezira by mouth with or without food.
- Use a measuring device marked for medicine dosing. Ask your pharmacist for help if you are unsure of how to measure your dose.
- If you miss a dose of Rezira, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

Ask your health care provider any questions you may have about how to use Rezira.

Detailed Rezira dosage information

# Important safety information

- Rezira may cause dizziness or drowsiness. These effects may be worse if you take it with alcohol or certain
  medicines. Use Rezira with caution. Do not drive or perform other possibly unsafe tasks until you know how you
  react to it.
- Do not take appetite suppressants while you are taking Rezira without checking with your doctor.
- Rezira has pseudoephedrine in it. Before you start any new medicine, check the label to see if it has
  pseudoephedrine in it too. If it does or if you are not sure, check with your doctor or pharmacist.
- Do NOT take more than the recommended dose or take for longer than prescribed without checking with your doctor.
- If your symptoms do not get better within 5 to 7 days or if they get worse, check with your doctor.
- Rezira may interfere with certain lab tests. Be sure your doctor and lab personnel know you are taking Rezira.
- Tell your doctor or dentist that you take Rezira before you receive any medical or dental care, emergency care, or surgery.
- Use Rezira with caution in the ELDERLY; they may be more sensitive to its effects.
- Rezira should be used with extreme caution in CHILDREN; safety and effectiveness in children have not been confirmed.
- PREGNANCY and BREAST-FEEDING: If you become pregnant, contact your doctor. You will need to discuss the
  benefits and risks of using Rezira while you are pregnant. It is not known if Rezira is found in breast milk. Do not
  breast-feed while taking Rezira.

### Rezira side effects

All medicines may cause side effects, but many people have no, or minor, side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome:

Dizziness; drowsiness, excitability; headache; nausea; nervousness or anxiety; trouble sleeping; weakness.

Seek medical attention right away if any of these SEVERE side effects occur:

 Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); difficulty urinating; fast or irregular heartbeat; hallucinations; seizures; severe dizziness, lightheadedness, or headache; severe drowsiness; tremor.

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your health

care provider. Call your doctor for medical advice about side effects. To report side effects to the appropriate agency, please read the Guide to Reporting Problems to FDA.



Rezira side effects (more detail)

# Related/similar drugs

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# If OVERDOSE is suspected:

Contact 1-800-222-1222 (the American Association of Poison Control Centers), your local poison control center, or emergency room immediately. Symptoms may include blurred vision; confusion; hallucinations; seizures; severe dizziness, lightheadedness, or headache; severe drowsiness; unusually fast, slow, or irregular heartbeat; vomiting.

# **Proper storage of Rezira**

Store Rezira at room temperature, between 59 and 86 degrees F (15 and 30 degrees C). Store away from heat, moisture, and light. Do not store in the bathroom. Keep Rezira out of the reach of children and away from pets.

### **General information**

- If you have any questions about Rezira, please talk with your doctor, pharmacist, or other health care provider.
- Rezira is to be used only by the patient for whom it is prescribed. Do not share it with other people.

- If your symptoms do not improve or if they become worse, check with your doctor.
- Check with your pharmacist about how to dispose of unused medicine.

This information is a summary only. It does not contain all information about Rezira. If you have questions about the medicine you are taking or would like more information, check with your doctor, pharmacist, or other health care provider.

# More about Rezira (hydrocodone / pseudoephedrine)

- · Check interactions
- Compare alternatives
- Reviews (6)
- Side effects
- Dosage information
- During pregnancy
- FDA approval history
- Drug class: upper respiratory combinations

### **Patient resources**

#### Other brands

Pancof HC

#### **Professional resources**

• Rezira prescribing information

### Related treatment guides

· Cough and Nasal Congestion

### **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

#### **DRUG STATUS**

Availability

Discontinued

**Pregnancy & Lactation** 

Risk data available

જુ 2	CSA Schedule* High potential for abuse	~
	Approval History Drug history at FDA	~
ကို	WADA Class Anti-Doping Classification	<b>~</b>

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