

**MEDICATION GUIDE**  
**HYCOFENIX® (Hye-koh-fee-niks)**  
**(hydrocodone bitartrate, pseudoephedrine hydrochloride, and guaifenesin)**  
**oral solution, C-II**

**What is the most important information I should know about HYCOFENIX?**

**HYCOFENIX is not for children under 18 years of age.**

**HYCOFENIX can cause serious side effects, including:**

- **Addiction, abuse and misuse.** Taking HYCOFENIX or other medicines that contain an opioid can cause addiction, abuse and misuse, which can lead to overdose and death. This can happen even if you take HYCOFENIX exactly as prescribed by your healthcare provider. Your risk of addiction, abuse, and misuse is increased if you or a family member has a history of drug or alcohol abuse or addiction, or mental health problems.
  - **Do not** share your HYCOFENIX with other people.
  - Keep HYCOFENIX in a safe place away from children.
- **Life-threatening breathing problems (respiratory depression).** HYCOFENIX can cause breathing problems (respiratory depression) that can happen at any time during treatment and can lead to death. Your risk of breathing problems is greatest when you first start taking HYCOFENIX, are taking other medicines that can cause breathing problems, have certain lung problems, are elderly, or have certain other health problems. **Children are at higher risk for respiratory depression.** Breathing problems can happen even if you take HYCOFENIX exactly as prescribed by your healthcare provider.

Call your healthcare provider or get emergency medical help right away if anyone taking HYCOFENIX has any of the symptoms below:

- increased sleepiness
- shallow breathing
- confusion
- limpness
- difficulty breathing

**Keep HYCOFENIX in a safe place away from children.** Accidental use of even 1 dose of HYCOFENIX, especially by a child, is a medical emergency and can cause breathing problems (respiratory depression) which can lead to death. If a child accidentally takes HYCOFENIX, get emergency medical help right away.

- **Overdose and death due to medicine dosing errors.** Overdose and death can happen if you measure the wrong dose of HYCOFENIX. Always use an accurate milliliter (mL) measuring device to measure the correct amount of HYCOFENIX. **Do not** use a household teaspoon to measure your medicine. You may accidentally take too much. You can ask your pharmacist for the measuring device and how to measure the correct dose.
- **Breathing problems (respiratory depression) that can lead to death and opioid withdrawal** can happen if you start taking or stop taking other medicines while taking HYCOFENIX, including:
  - certain antibiotics
  - certain medicines to treat a fungal infection
  - certain medicines to treat Human Immunodeficiency Virus (HIV)-1 infection, Acquired Immune Deficiency Syndrome (AIDS), or Hepatitis C
  - rifampin
  - carbamazepine
  - phenytoin

Tell your healthcare provider if you take any of these medicines. Ask your healthcare provider or pharmacist if you are not sure if your medicine is one listed above.

- **Severe drowsiness, breathing problems (respiratory depression), coma, and death** can happen in people who take HYCOFENIX with benzodiazepines or other central nervous system depressants, including alcohol.
  - **Do not** take benzodiazepines or any medicine that can cause drowsiness or sleepiness during treatment with HYCOFENIX.
  - **Do not** drink alcohol or take prescription or over-the-counter medicines that contain alcohol during treatment with HYCOFENIX.
- **Opioid withdrawal in a newborn.** Use of HYCOFENIX during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated. You should not take HYCOFENIX if you are pregnant. Tell your healthcare provider right away if you are pregnant or think you may be pregnant.

**What is HYCOFENIX?**

- HYCOFENIX is a prescription medicine used in adults to treat cough, a stuffy nose (nasal congestion), and loosen mucus that you can have with a common cold. HYCOFENIX contains 3 medicines, hydrocodone, pseudoephedrine and guaifenesin. Hydrocodone is an opioid (narcotic) cough suppressant. Pseudoephedrine is a decongestant. Guaifenesin is an expectorant.
- **HYCOFENIX is a federal controlled substance (C-II) because it contains hydrocodone that can be abused or lead to dependence.** Keep HYCOFENIX in a safe place to prevent misuse and abuse. Selling or giving away HYCOFENIX may harm others, and is against the law. Tell your healthcare provider if you have abused or been dependent on alcohol, prescription medicines or street drugs.

**Who should not take HYCOFENIX?**

**HYCOFENIX is not for children under 18 years of age. See “What is the most important information I should know about HYCOFENIX?”**

**Do not take HYCOFENIX if you:**

- have severe breathing problems (respiratory depression) or breathing problems caused by asthma. See “**What is the most important information I should know about HYCOFENIX?**”
- have a blockage (obstruction) in your bowel such as a paralytic ileus.
- have a type of glaucoma called “narrow angle glaucoma”.
- have problems emptying your bladder (urinary retention).
- have severe high blood pressure or certain heart problems (severe coronary artery disease).
- are allergic to hydrocodone, pseudoephedrine, guaifenesin, or any of the ingredients in HYCOFENIX. See the end of this Medication Guide for a complete list of ingredients.

**Ask your healthcare provider if you have any questions about this information.**

**Before you take HYCOFENIX, tell your healthcare provider about all of your medical conditions, including if you:**

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| • have a drug addiction                          | • have glaucoma (increased pressure in your eyes)               |
| • have lung or breathing problems                | • have prostate problems  |
| • have a fever and are coughing up mucus         | • have problems with your urinary tract or difficulty urinating |
| • have had a recent head injury                  | • have kidney or liver problems                                 |
| • have had a brain tumor or other brain problems | • have heart or blood vessel (cardiovascular) problems          |
| • have or have had seizures                      | • have adrenal gland problems                                   |
| • have pain in your stomach-area (abdomen)       | • plan to have surgery  |
| • have constipation or other bowel problems      | • have low blood pressure                                       |
| • have bile duct or pancreas problems            |   |
- are pregnant or plan to become pregnant. HYCOFENIX can harm your unborn baby. See “**What is the most important information I should know about HYCOFENIX?**”
  - are breastfeeding or plan to breastfeed. Hydrocodone and pseudoephedrine pass into your breast milk and can cause serious side effects in your baby including increased sleepiness, irritability, breathing problems (respiratory depression), and death. You and your healthcare provider should decide if you will take HYCOFENIX or breastfeed. You should not do both. See “**What should I avoid while taking HYCOFENIX?**”
  - plan to have children. HYCOFENIX may affect the ability to have a child in females and males (fertility problems). It is not known if these fertility problems will be reversible, even after you stop taking HYCOFENIX. Talk to your healthcare provider if this is a concern for you.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Taking HYCOFENIX with certain other medicines can cause side effects or affect how well HYCOFENIX or the other medicines work. Do not start or stop taking other medicines without talking to your healthcare provider.

**Especially tell your healthcare provider if you:**

- take pain medicines such as opioids (narcotics).
- take cold or allergy medicines that contain antihistamines or cough suppressants.
- drink alcohol.
- take muscle relaxants.
- take certain medicines used to treat mood, anxiety, psychotic or thought disorders, or depression, including monoamine oxidase inhibitors (MAOIs), tricyclics, selective serotonin reuptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), or antipsychotics.
- take medicines to lower your blood pressure.
- take water pills (diuretics).
- take medicines called “anticholinergics” used to treat certain health problems including asthma, chronic obstructive pulmonary disease (COPD), or stomach problems.
- take a medicine called “digitalis” used to treat certain heart problems.

Ask your healthcare provider if you are not sure if you take one of these medicines.

**How should I take HYCOFENIX?**

- See “**What is the most important information I should know about HYCOFENIX?**”
- Take HYCOFENIX exactly as your healthcare provider tells you to take it. Do not change your dose without talking to your healthcare provider.
- Take HYCOFENIX using an accurate milliliter (mL) measuring device. If you do not have one, ask your pharmacist to give you a measuring device to help you measure the correct amount of HYCOFENIX. **Do not use a household teaspoon to measure your medicine. You may accidentally take too much.**
- **Do not** overfill the measuring device.

- Rinse your measuring device with water after each use.
- If you take too much HYCOFENIX, call your healthcare provider or go to the nearest hospital emergency room right away.
- Tell your healthcare provider if your cough does not get better within 5 days of treatment with HYCOFENIX.

#### **What should I avoid while taking HYCOFENIX?**

- Avoid driving a car or operating machinery during treatment with HYCOFENIX. HYCOFENIX can cause you to be drowsy, slow your thinking and motor skills, and affect your vision.
- **Do not** drink alcohol during treatment with HYCOFENIX. Drinking alcohol can increase your chances of having serious side effects.

#### **Avoid the use of HYCOFENIX if you:**

- are pregnant. Use of HYCOFENIX during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated. Tell your healthcare provider right away if you are pregnant or think you may be pregnant.
- are breastfeeding. Use of HYCOFENIX while breastfeeding can cause severe breathing problems (respiratory depression) in your breastfed infant that could be life-threatening.
- take a medicine called a monoamine oxidase inhibitor (MAOI). Avoid taking an MAOI within 14 days after you stop taking HYCOFENIX. Avoid starting HYCOFENIX if you stopped taking an MAOI in the last 14 days.

#### **What are the possible side effects of HYCOFENIX?**

##### **HYCOFENIX can cause serious side effects, including:**

- See “**What is the most important information I should know about HYCOFENIX?**”
- **Bowel problems including severe constipation or stomach pain.** See “**Who should not take HYCOFENIX?**”
- **Increased pressure in your head (intracranial).** Avoid the use of HYCOFENIX if you have a head injury or have been told that you have changes in the tissue of your brain (brain lesions) or increased pressure in your head.
- **Heart and blood vessel (cardiovascular) and central nervous system (CNS) effects.** Cardiovascular and CNS effects can happen in some people during treatment with HYCOFENIX, including trouble sleeping (insomnia), dizziness, weakness, tremors, temporary increases in blood pressure, abnormal heart beats (arrhythmias), seizures, and feeling faint. Call your healthcare provider right away if you have any of these symptoms.
- **Low blood pressure.** A sudden drop in blood pressure can happen in some people during treatment with HYCOFENIX and this may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension). Your risk of having this problem may be increased if you take HYCOFENIX with certain other medicines that lower blood pressure. If you have any of these symptoms while taking HYCOFENIX, sit or lie down. Do not change your body position too fast. Get up slowly from sitting or lying down.
- **Adrenal gland problems.** HYCOFENIX can cause serious and life-threatening adrenal gland problems. Your healthcare provider may do blood tests to check for adrenal gland problems. Call your healthcare provider right away if you have any of these symptoms:
  - nausea
  - vomiting
  - not wanting to eat (anorexia)
  - fatigue
  - weakness
  - dizziness
  - low blood pressure

##### **The most common side effects of HYCOFENIX include:**

- |   |                                |
|---|--------------------------------|
| • sleepiness                                  | • nausea                       |
| • confusion                                   | • vomiting                     |
| • coordination problems                       | • constipation                 |
| • decrease in mental and physical performance | • fast or irregular heart beat |
| • lack of energy                              | • irritability                 |
| • lightheadedness                             | • anxiety                      |
| • dizziness                                   | • restlessness                 |
| • headache                                    | • nervousness                  |
| • dry mouth                                   | • tremor                       |

These are not all the possible side effects of HYCOFENIX.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **How should I store HYCOFENIX?**

- Store HYCOFENIX at room temperature between 68°F to 77°F (20°C to 25°C).
- Store HYCOFENIX in a tightly closed container, in a dry, cool place away from heat or direct sunlight.
- **Keep HYCOFENIX and all medicines out of the reach of children.**

#### **How should I store dispose of HYCOFENIX?**

Remove unused HYCOFENIX from the container and mix it with an undesirable, non-toxic substance such as cat litter or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a

sealed plastic bag and throw it away in the household trash. You can also follow your state or local guidelines on how to safely throw away HYCOFENIX.

**General information about the safe and effective use of HYCOFENIX.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use HYCOFENIX for a condition for which it was not prescribed. Do not give HYCOFENIX to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about HYCOFENIX that is written for health professionals.

**What are the ingredients in HYCOFENIX?**

**Active Ingredients:** hydrocodone bitartrate, pseudoephedrine hydrochloride, and guaifenesin

**Inactive Ingredients:** black raspberry flavor, citric acid, D&C Red #33, FD&C Blue #1, glycerin, methylparaben, polyethylene glycol propylparaben, purified water, saccharin sodium, sodium citrate, and sorbitol

Manufactured for: BKK Pharmaceuticals, LLC Wilmington, DE 19801  
For more information, go to [www.hycofenix.com](http://www.hycofenix.com) or call 1-800-298-1087.



This Medication Guide has been approved by the U.S. Food and Drug Administration.

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