

MEDICATION GUIDE

HYDROCODONE AND HOMATROPINE

(hye" droe koe' done hoe mat' roe peen)

(hydrocodone bitartrate and homatropine methylbromide) syrup, CII

What is the most important information I should know about HYDROCODONE AND HOMATROPINE?

- Taking HYDROCODONE AND HOMATROPINE with benzodiazepines or other central nervous system depressants, including alcohol can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.
- HYDROCODONE AND HOMATROPINE can cause you to be drowsy. Avoid driving a car or operating machinery during the treatment with HYDROCODONE AND HOMATROPINE. Women who breastfeed should talk to their healthcare provider before taking HYDROCODONE AND HOMATROPINE.
- Call your healthcare provider or get emergency medical help right away if anyone taking HYDROCODONE AND HOMATROPINE has any of the symptoms below:
 - increased sleepiness
 - confusion
 - difficulty breathing
 - shallow breathing
 - limpness
 - your baby has difficulty breastfeeding
- Keep HYDROCODONE AND HOMATROPINE in a safe place away from children. Accidental use by a child is a medical emergency and can cause death. If a child accidentally takes HYDROCODONE AND HOMATROPINE, get emergency medical help right away.
- HYDROCODONE AND HOMATROPINE can cause serious side effects including death.
- Take HYDROCODONE AND HOMATROPINE exactly as prescribed by your healthcare provider. If you take the wrong dose of HYDROCODONE AND HOMATROPINE, you could overdose and die.
- HYDROCODONE AND HOMATROPINE is not for children under 6 years of age.

What is HYDROCODONE AND HOMATROPINE?

- HYDROCODONE AND HOMATROPINE is a prescription medicine used to treat a cough in adults and children 6 years and older. HYDROCODONE AND HOMATROPINE contains hydrocodone and is a narcotic cough suppressant.
- **HYDROCODONE AND HOMATROPINE is a federal controlled substance (C-II) because it contains hydrocodone that can be abused or lead to dependence.** Keep HYDROCODONE AND HOMATROPINE in a safe place to prevent misuse and abuse. Selling or giving away HYDROCODONE AND HOMATROPINE may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- HYDROCODONE AND HOMATROPINE is not for children under 6 years of age.

Who should not take HYDROCODONE AND HOMATROPINE?

- Do not take HYDROCODONE AND HOMATROPINE if you are allergic to hydrocodone or homatropine methylbromide. See the end of this Medication Guide for a complete list of ingredients.

Before you take HYDROCODONE AND HOMATROPINE, tell your healthcare provider about all of your medical conditions, including if you:

- have a drug dependence
- have lung or breathing problems
- have had a head injury
- have pain in your stomach-area (abdomen)

- have a history of severe or persistent cough
- have prostate problems
- plan to have surgery
- drink alcohol
- have kidney or liver problems
- have diabetes
- have thyroid problems, such as hypothyroidism
- have problems with your urinary tract (urethral stricture)
- are pregnant or plan to become pregnant. It is not known if HYDROCODONE AND HOMATROPINE will harm your unborn baby. You and your healthcare provider should decide if you should take HYDROCODONE AND HOMATROPINE while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if HYDROCODONE AND HOMATROPINE passes into your breast milk. You and your healthcare provider should decide if you will take HYDROCODONE AND HOMATROPINE or breastfeed. You should not do both.

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

Taking HYDROCODONE AND HOMATROPINE with certain other medicines can cause side effects or affect how well HYDROCODONE AND HOMATROPINE or the other medicines work.

Do not start or stop other medicines without talking to your healthcare provider. Especially tell your healthcare provider if you:

- take pain medicines such as narcotics
- take cold or allergy medicines that contain antihistamines or cough suppressants
- take medicines for mental illness (anti-psychotics, anti-anxiety)
- drink alcohol
- take medicines for depression, including monoamine oxidase inhibitors (MAOIs) and tricyclics

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

How should I take HYDROCODONE AND HOMATROPINE?

- Take HYDROCODONE AND HOMATROPINE exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much HYDROCODONE AND HOMATROPINE to take and when to take it. Do not change your dose without talking to your healthcare provider.
- Ask your pharmacist to give you a measuring device to help you measure the correct amount of HYDROCODONE AND HOMATROPINE. **Do not use a household teaspoon to measure your medicine. You may accidentally take too much.** If you take too much HYDROCODONE AND HOMATROPINE, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking HYDROCODONE AND HOMATROPINE?

- HYDROCODONE AND HOMATROPINE can cause you to be drowsy. Avoid driving a car or operating machinery while you take HYDROCODONE AND HOMATROPINE until you know how it affects you.
- Avoid drinking alcohol while taking HYDROCODONE AND HOMATROPINE. Drinking alcohol can increase your chances of having serious side effects.

What are the possible side effects of HYDROCODONE AND HOMATROPINE?

HYDROCODONE AND HOMATROPINE may cause serious side effects, including:

- See "[**What is the most important information I should know about HYDROCODONE AND HOMATROPINE?**](#)"

- **Breathing problems (respiratory depression) which can lead to death.** Call your healthcare provider or get emergency treatment right away if you are sleeping more than usual, have shallow slow breathing, or confusion.
- **Physical dependence or abuse.** Take HYDROCODONE AND HOMATROPINE exactly as your healthcare provider tells you to take it. Stopping HYDROCODONE AND HOMATROPINE suddenly could cause withdrawal symptoms.
- **Bowel problems including constipation or stomach pain.**
- **Increased intracranial pressure.**

The most common side effects of HYDROCODONE AND HOMATROPINE include:

- sleepiness
- confusion
- nausea and vomiting
- difficulty urinating
- trouble breathing

These are not all the possible side effects of HYDROCODONE AND HOMATROPINE.

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 HYDROCODONE AND HOMATROPINE?

- Store HYDROCODONE AND HOMATROPINE syrup at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep HYDROCODONE AND HOMATROPINE syrup, and all medicines out of the reach of children.**

General information about the safe and effective use of HYDROCODONE AND HOMATROPINE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use HYDROCODONE AND HOMATROPINE for a condition for which it was not prescribed. Do not give HYDROCODONE AND HOMATROPINE 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 HYDROCODONE AND HOMATROPINE that is written for health professionals.

What are the ingredients in HYDROCODONE AND HOMATROPINE?

Active ingredient: hydrocodone bitartrate and homatropine methylbromide.

Inactive ingredients in HYDROCODONE AND HOMATROPINE syrup: Caramel, NF; Cherry Flavor; D&C Red No. 33; Glycerin, USP; Liquid Sugar; Methylparaben, NF; Propylene Glycol, USP; Propylparaben, NF and Sorbitol Solution, USP. Citric Acid, USP or Sodium Citrate, USP may be added for pH adjustment

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