

## DISCLAIMER

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# Hydrocodone Bitartrate and Homatropine Methylbromide Syrup (High-droe-KOE-dohn by-TAR-trate/hoe-MAT-troe-peen Meth-ill-BROE-mide)



## MEDICATION GUIDE

### What is the most important information I should know about Hydrocodone Bitartrate and Homatropine Methylbromide Syrup?

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

### What is Hydrocodone Bitartrate and Homatropine Methylbromide Syrup?

- Hydrocodone Bitartrate and Homatropine Methylbromide Syrup is a prescription medicines used to treat a cough in adults and children 6 years and older. Hydrocodone Bitartrate and Homatropine Methylbromide Syrup contain hydrocodone and is a narcotic cough suppressant.
- **Hydrocodone Bitartrate and Homatropine Methylbromide Syrup is a federal controlled substances (C-II) because they contain hydrocodone that can be abused or lead to dependence.** Keep Hydrocodone Bitartrate and Homatropine Methylbromide Syrup in a safe place to prevent misuse and abuse. Selling or giving away Hydrocodone Bitartrate and Homatropine Methylbromide Syrup 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 Bitartrate and Homatropine Methylbromide Syrup is not for children under 6 years of age.

### Who should not take Hydrocodone Bitartrate and Homatropine Methylbromide Syrup?

- Do not take Hydrocodone Bitartrate and Homatropine Methylbromide Syrup 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 Bitartrate and Homatropine Methylbromide Syrup, tell your healthcare provider about all of your medical conditions, including if you:

- have a drug dependence
- plan to have surgery
- have lung or breathing problems
- drink alcohol
- have had a head injury
- have kidney or liver problems
- have pain in your stomach-area (abdomen)
- have diabetes
- have a history of severe or persistent cough
- have thyroid problems, such as hypothyroidism
- have prostate problems
- have problems with your urinary tract (urethral stricture)
- are pregnant or plan to become pregnant. It is not known if Hydrocodone Bitartrate and Homatropine Methylbromide Syrup will harm your unborn baby. You and your healthcare provider should decide if you should take Hydrocodone Bitartrate and Homatropine Methylbromide Syrup while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if Hydrocodone Bitartrate and Homatropine Methylbromide pass into your breast milk. You and your healthcare provider should decide if you will take Hydrocodone Bitartrate and Homatropine Methylbromide Syrup 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 Bitartrate and Homatropine Methylbromide Syrup with certain other medicines can cause side effects or affect how well Hydrocodone Bitartrate and Homatropine Methylbromide Syrup 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 Bitartrate and Homatropine Methylbromide Syrup?

- Take Hydrocodone Bitartrate and Homatropine Methylbromide Syrup exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much Hydrocodone Bitartrate and Homatropine Methylbromide Syrup 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 Bitartrate and Homatropine Methylbromide Syrup. **Do not use a household teaspoon to measure your medicine. You may accidentally take too much.** If you take too much Hydrocodone Bitartrate and Homatropine Methylbromide Syrup, call your healthcare provider or go to the nearest hospital emergency room right away.

### What should I avoid while taking Hydrocodone Bitartrate and Homatropine Methylbromide Syrup?

- **Hydrocodone Bitartrate and Homatropine Methylbromide Syrup can cause you to be drowsy. Avoid driving a car or operating machinery during treatment with Hydrocodone Bitartrate and Homatropine Methylbromide Syrup.**
- **Avoid drinking alcohol during treatment with Hydrocodone Bitartrate and Homatropine Methylbromide Syrup. Drinking alcohol can increase your chances of having serious side effects.**

### What are the possible side effects of Hydrocodone Bitartrate and Homatropine Methylbromide Syrup?

**Hydrocodone Bitartrate and Homatropine Methylbromide Syrup may cause serious side effects, including:**

- See “What is the most important information I should know about Hydrocodone Bitartrate and Homatropine Methylbromide Syrup?”
- **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 Bitartrate and Homatropine Methylbromide Syrup exactly as your healthcare provider tells you to take it. Stopping Hydrocodone Bitartrate and Homatropine Methylbromide Syrup suddenly could cause withdrawal symptoms.
- **Bowel problems including constipation or stomach pain.**
- **Increased intracranial pressure**

**The most common side effects of Hydrocodone Bitartrate and Homatropine Methylbromide Syrup include:**

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

These are not all the possible side effects of Hydrocodone Bitartrate and Homatropine Methylbromide Syrup.

Call your doctor for medical advice about side effects. You may report side effects to Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088.

### How should I store Hydrocodone Bitartrate and Homatropine Methylbromide Syrup?

- Store Hydrocodone Bitartrate and Homatropine Methylbromide Syrup at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep Hydrocodone Bitartrate and Homatropine Methylbromide Syrup, and all medicines out of the reach of children.**

### General information about the safe and effective use of Hydrocodone Bitartrate and Homatropine Methylbromide Syrup.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Hydrocodone Bitartrate and Homatropine Methylbromide Syrup for a condition for which it was not prescribed. Do not give Hydrocodone Bitartrate and Homatropine Methylbromide Syrup 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 Bitartrate and Homatropine Methylbromide Syrup that is written for health professionals.

### What are the ingredients in Hydrocodone Bitartrate and Homatropine Methylbromide Syrup?

**Active ingredient:** hydrocodone bitartrate and homatropine methylbromide.

**Inactive ingredients in Hydrocodone Bitartrate and Homatropine Methylbromide Syrup:** Caramel color, cherry flavor, citric acid, FD&C Red #40, methylparaben, propylparaben, purified water, sorbitol solution and sucrose syrup. Citric acid and/or sodium citrate may be added to adjust pH.

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

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