

MEDICATION GUIDE

Hydrocodone Bitartrate (HIGH-droe-KOE-dohn by-TAR-trate) and Homatropine Methylbromide (hoe-MAT-troe-peen METH-ill-BROE-mide) Oral Solution, CII

What is the most important information I should know about hydrocodone bitartrate and homatropine methylbromide oral solution?

- Taking hydrocodone bitartrate and homatropine methylbromide oral solution 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 oral solution can cause you to be drowsy. Do not drive a car or operate machinery until you know how hydrocodone bitartrate and homatropine methylbromide oral solution affects you. Hydrocodone bitartrate and homatropine methylbromide oral solution can slow your thinking and motor skills, and may affect your vision.
- Women who breastfeed should talk to their healthcare provider before taking hydrocodone bitartrate and homatropine methylbromide oral solution.
- Call your healthcare provider or get emergency medical help right away if anyone taking hydrocodone bitartrate and homatropine methylbromide oral solution has any of the symptoms below:
 - o increased sleepiness
 - o confusion
 - o difficulty breathing
 - o shallow breathing
 - o limpness
 - o your baby has difficulty breastfeeding
- Keep hydrocodone bitartrate and homatropine methylbromide oral solution 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 oral solution, get emergency medical help right away.
- Hydrocodone bitartrate and homatropine methylbromide oral solution can cause serious side effects including death.
- Take hydrocodone bitartrate and homatropine methylbromide oral solution exactly as prescribed by your healthcare provider. If you take the wrong dose of hydrocodone bitartrate and homatropine methylbromide oral solution, you could overdose and die.
- Hydrocodone bitartrate and homatropine methylbromide oral solution is not for children under 6 years of age.

What is hydrocodone bitartrate and homatropine methylbromide oral solution?

- Hydrocodone bitartrate and homatropine methylbromide oral solution is a prescription medicine used to treat a cough in adults and children 6 years and older. Hydrocodone bitartrate and homatropine methylbromide oral solution contains hydrocodone and is a narcotic cough suppressant.
- Hydrocodone bitartrate and homatropine methylbromide oral solution **is a federal controlled substance (C-II) because it contains hydrocodone that can be abused or lead to dependence.** Keep hydrocodone bitartrate and homatropine methylbromide oral solution in a safe place to prevent misuse and abuse. Selling or giving away hydrocodone bitartrate and homatropine methylbromide oral solution 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 oral solution is not for children under 6 years of age.

Who should not take hydrocodone bitartrate and homatropine methylbromide oral solution?

- Do not take hydrocodone bitartrate and homatropine methylbromide oral solution 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 oral solution, tell your healthcare provider about all of your medical conditions, including if you:

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| ◦ 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 will harm your unborn baby. You and your healthcare provider should decide if you should take hydrocodone bitartrate and homatropine methylbromide oral solution while you are pregnant. | |
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- are breastfeeding or plan to breastfeed. It is not known if hydrocodone bitartrate and homatropine methylbromide passes into your breast milk. You and your healthcare provider should decide if you will take hydrocodone bitartrate and homatropine methylbromide oral solution or breastfeed. You should not do both.
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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 oral solution with certain other medicines can cause side effects or affect how well hydrocodone bitartrate and homatropine methylbromide oral solution 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

How should I take hydrocodone bitartrate and homatropine methylbromide oral solution?

- Take hydrocodone bitartrate and homatropine methylbromide oral solution exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much hydrocodone bitartrate and homatropine methylbromide oral solution 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 oral solution. **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 oral solution, 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 oral solution?

- Hydrocodone bitartrate and homatropine methylbromide oral solution can cause you to be drowsy. Do not drive a car or use machinery while you take hydrocodone bitartrate and homatropine methylbromide oral solution until you know how it affects you.
- Avoid drinking alcohol while taking hydrocodone bitartrate and homatropine methylbromide oral solution. Drinking alcohol can increase your chances of having serious side effects.

What are the possible side effects of hydrocodone bitartrate and homatropine methylbromide oral solution?

Hydrocodone bitartrate and homatropine methylbromide oral solution may cause serious side effects, including:

- See “What is the most important information I should know about hydrocodone bitartrate and homatropine methylbromide oral solution?”
- **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 or slow breathing, or confusion.
- **Physical dependence or abuse.** Take hydrocodone bitartrate and homatropine methylbromide oral solution exactly as your healthcare provider tells you to take it. Stopping hydrocodone bitartrate and homatropine methylbromide oral solution suddenly could cause withdrawal symptoms.
- **Bowel problems including constipation or stomach pain.**

The most common side effects of hydrocodone bitartrate and homatropine methylbromide oral solution include:

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

These are not all the possible side effects of hydrocodone bitartrate and homatropine methylbromide oral solution.

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 bitartrate and homatropine methylbromide oral solution?

- Store hydrocodone bitartrate and homatropine methylbromide oral solution at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep hydrocodone bitartrate and homatropine methylbromide oral solution, and all medicines out of the reach of children.**

General information about the safe and effective use of hydrocodone bitartrate and homatropine methylbromide oral solution.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use hydrocodone bitartrate and homatropine methylbromide oral solution for a condition for which it was not prescribed. Do not give hydrocodone bitartrate and homatropine methylbromide oral solution 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 oral solution that is written for health professionals. For more information please contact Actavis at 1-800-432-8534 .

What are the ingredients in hydrocodone bitartrate and homatropine methylbromide oral solution?

Active ingredient: hydrocodone bitartrate, USP and homatropine methylbromide, USP.

Inactive ingredients: artificial cherry flavor, anhydrous citric acid, D&C Red #33, FD&C Blue #1, FD&C Red #40, methylparaben, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate dihydrate, sucrose.

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

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