

MEDICATION GUIDE

Hydrocodone Bitartrate (hye'' droe koe' done bye tar' trate) and Homatropine Methylbromide (hoe mat' roe peen meth'' il broe' mide) Tablets, USP CII

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

Hydrocodone Bitartrate and Homatropine Methylbromide Tablets is not for children under 18 years of age.

Hydrocodone Bitartrate and Homatropine Methylbromide Tablets can cause serious side effects, including:

- **Addiction, abuse and misuse.** Taking Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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.
 - o **Do not** share your Hydrocodone Bitartrate and Homatropine Methylbromide Tablets with other people.
 - o Keep Hydrocodone Bitartrate and Homatropine Methylbromide Tablets in a safe place away from children.
- **Life-threatening breathing problems (respiratory depression).** Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets exactly as prescribed by your healthcare provider. Call your healthcare provider or get emergency medical help right away if anyone taking Hydrocodone Bitartrate and Homatropine Methylbromide Tablets has any of the symptoms below:
 - o increased sleepiness
 - o shallow breathing
 - o confusion
 - o limpness
 - o difficulty breathing

Keep Hydrocodone Bitartrate and Homatropine Methylbromide Tablets in a safe place away from children. Accidental use of even 1 dose of Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, get emergency medical help right away.

- **Overdose and death due to medicine dosing errors.**
- **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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, including:
 - o certain antibiotics
 - o certain medicines to treat a fungal infection
 - o certain medicines to treat Human Immunodeficiency Virus (HIV)-1 infection, Acquired Immune Deficiency Syndrome (AIDS), or Hepatitis C
 - o rifampin
 - o carbamazepine
 - o 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 listed above.

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

What is Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?

- Hydrocodone Bitartrate and Homatropine Methylbromide Tablets is a prescription medicine used in adults to treat a cough. Hydrocodone Bitartrate and Homatropine Methylbromide Tablets contains hydrocodone, an opioid (narcotic) cough suppressant.
- **Hydrocodone Bitartrate and Homatropine Methylbromide Tablets is a federal controlled substance (CII) because it contains hydrocodone that can be abused or lead to dependence.** Keep Hydrocodone Bitartrate and Homatropine Methylbromide Tablets in a safe place to prevent misuse and abuse. Selling or giving away Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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.

Who should not take Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?

Hydrocodone Bitartrate and Homatropine Methylbromide Tablets is not for children under 18 years of age. See "What is the most important information I should know about Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?"

Do not take Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?"
- have a blockage (obstruction) in your bowel such as a paralytic ileus.
- are allergic to hydrocodone, homatropine, or any of the ingredients in Hydrocodone Bitartrate and Homatropine Methylbromide Tablets. 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have a drug addiction
- have lung or breathing problems
- have a fever and are coughing up mucus
- have had a recent head injury
- have had a brain tumor or other brain problems
- have or have had seizures
- have pain in your stomach-area (abdomen)
- have constipation or other bowel problems
- are pregnant or plan to become pregnant. Hydrocodone Bitartrate and Homatropine Methylbromide Tablets can harm your unborn baby. See "What is the most important information I should know about Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?"
- are breastfeeding or plan to breastfeed. Hydrocodone passes into your breast milk and can cause serious side effects in your baby including increased sleepiness, breathing problems (respiratory depression), and death. You and your healthcare provider should decide if you will take Hydrocodone Bitartrate and Homatropine Methylbromide Tablets or breastfeed. You should not do both. See "What should I avoid while taking Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?"
- plan to have children. Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets. 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets with certain other medicines can cause side effects or affect how well Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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.

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NP Item#: NOVE-NP_40741	Size: 6 x 17.75 (folded: 6 x 4.5)	Type size:	
PO No.:	Item Iss./Rev. Date: Rev. 11/2018	Cust. Part No.: MG118000203	
Customer: Novel	Private Label:	Description: Hydrocodone Bit & Homatropine Methyl Tabs MG118000203	
Bar code details: Type: Code:			
Notes:			
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- 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.
- 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 Tablets?

- See “**What is the most important information I should know about Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?**”
- Take Hydrocodone Bitartrate and Homatropine Methylbromide Tablets exactly as your healthcare provider tells you to take it. Do not change your dose without talking to your healthcare provider.
- Take Hydrocodone Bitartrate and Homatropine Methylbromide Tablets by mouth only.
- If you take too much Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets.

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

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

Avoid the use of Hydrocodone Bitartrate and Homatropine Methylbromide Tablets if you:

- are pregnant. Use of Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets. Avoid starting Hydrocodone Bitartrate and Homatropine Methylbromide Tablets if you stopped taking an MAOI in the last 14 days.

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

Hydrocodone Bitartrate and Homatropine Methylbromide Tablets can cause serious side effects, including:

- See “**What is the most important information I should know about Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?**”
- **Bowel problems including severe constipation or stomach pain.** See “**Who should not take Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?**”
- **Increased pressure in your head (intracranial).** Avoid the use of Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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.
- **Increased risk of seizures in people with seizure disorders.** If you have a seizure disorder, Hydrocodone Bitartrate and Homatropine Methylbromide Tablets may increase how often you have a seizure.
- **Low blood pressure.** A sudden drop in blood pressure can happen in some people during treatment with Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets with certain other medicines that lower blood pressure. If you have any of these symptoms while taking Hydrocodone Bitartrate and Homatropine Methylbromide Tablets, sit or lie down. Do not change your body position too fast. Get up slowly from sitting or lying down.
- **Adrenal gland problems.** Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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:

o nausea	o weakness
o vomiting	o dizziness
o not wanting to eat (anorexia)	o low blood pressure
o fatigue	

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

- | | |
|---|----------------|
| • sleepiness | • dizziness |
| • confusion | • headache |
| • coordination problems | • dry mouth |
| • decrease in mental and physical performance | • nausea |
| • lack of energy | • vomiting |
| • lightheadedness | • constipation |

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

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 Tablets?

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

How should I dispose of Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?

Remove unused Hydrocodone Bitartrate and Homatropine Methylbromide Tablets 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 Hydrocodone Bitartrate and Homatropine Methylbromide Tablets.

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

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

What are the ingredients in Hydrocodone Bitartrate and Homatropine Methylbromide Tablets?

Active ingredient: hydrocodone bitartrate and homatropine methylbromide.

Inactive ingredients in Hydrocodone Bitartrate and Homatropine Methylbromide Tablets: anhydrous lactose, dicalcium phosphate anhydrous, sodium starch glycolate, colloidal silicon dioxide and magnesium stearate.

Manufactured by:
Novel Laboratories, Inc.
400 Campus Drive,
Somerset, NJ 08873

Manufactured For:
Lupin Pharmaceuticals Inc.
Baltimore, MD 21202

For more information, call 1-866-403-7592.

MG1180000203 Rev. 11/2018

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