HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE- hydrocodone bitartrate and homatropine methylbromide syrup
Morton Grove Pharmaceuticals, Inc.

HYDROCODONE BITARTRATE
and HOMATROPINE METHYLBROMIDE SYRUP
CII

Rx only

WARNING RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death (see Warnings, Precautions - Drug Interactions). Avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol.

DESCRIPTION

This product contains hydrocodone (dihydrocodeinone) bitartrate, a semisynthetic centrally acting opioid antitussive. Homatropine Methylbromide is included in a subtherapeutic amount to discourage deliberate overdosage.

Each 5 mL (teaspoonful) contains:

Hydrocodone Bitartrate, USP . . . . . 5 mg

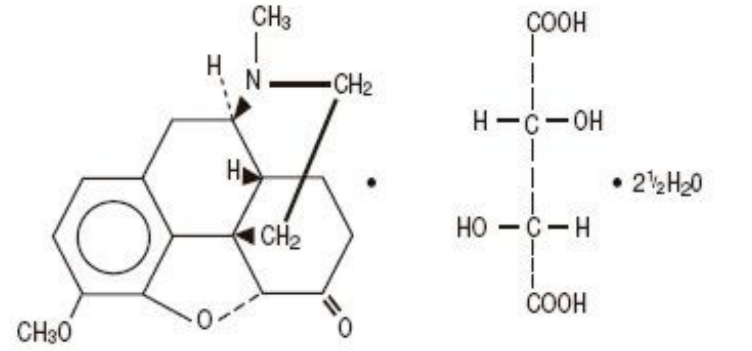
Homatropine Methylbromide, USP . . . . 1.5 mg

Alcohol . . . . . less than 0.1%

(contributed by flavorings)

Also contains: 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.

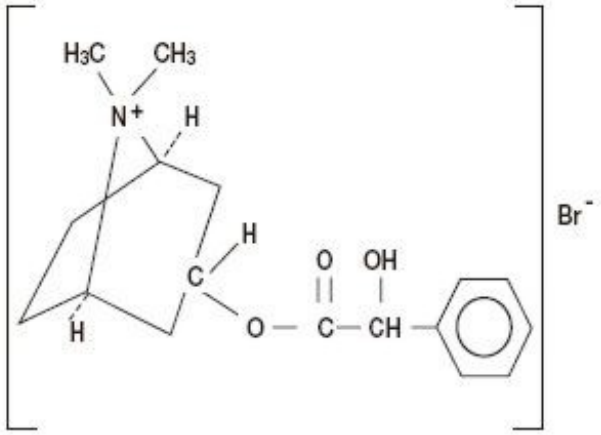
The hydrocodone component is 4,5α-epoxy-3-methoxy-17-methylmorphinan-6-one tartrate (1:1) hydrate (2:5), a fine white crystal or crystalline powder, which is derived from the opium alkaloid, thebaine, and has the following structural formula:



$C_{18}H_{21}NO_3 \cdot C_4H_6O_6 \cdot 2\frac{1}{2}H_2O$ M.W.494.50

HYDROCODONE BITARTRATE

Homatropine Methylbromide is 8-Azoniabicyclo[3.2.1]octane,3-[(hydroxyphenylacetyl)-oxy]-8,8-dimethyl-, bromide,endo-; a white crystal or fine white crystalline powder, and has the following structural formula:



$C_{17}H_{24}BrNO_3$ M.W. 370.29

HOMATROPINE METHYLBROMIDE

CLINICAL PHARMACOLOGY

Hydrocodone is a semisynthetic opioid anti-tussive and analgesic with multiple actions qualitatively similar to those of codeine. The precise mechanism of action of hydrocodone and other opiates is not known; however, hydrocodone is believed to act directly on the cough center. In excessive doses, hydrocodone, like other opium derivatives, will depress respiration. The effects of hydrocodone in therapeutic doses on the cardiovascular system are insignificant. Hydrocodone can produce miosis, euphoria, physical and physiological dependence.

Following a 10 mg oral dose of hydrocodone administered to five adult male subjects, the mean peak concentration was 23.6 ± 5.2 ng/mL. Maximum serum levels were achieved at 1.3 ± 0.3 hours and the half-life was determined to be 3.8 ± 0.3 hours. Hydrocodone exhibits a complex pattern of metabolism including O-demethylation, N-demethylation and 6-keto reduction to the corresponding 6-α-and 6-β-hydroxymetabolites.

INDICATIONS AND USAGE

Hydrocodone bitartrate and homatropine methylbromide syrup is indicated for the symptomatic relief of

cough in adults and children 6 years of age and older.

CONTRAINDICATIONS

Hydrocodone bitartrate and homatropine methylbromide syrup should not be administered to patients who are hypersensitive to hydrocodone or homatropine methylbromide.

WARNINGS

Risks from Concomitant Use with Benzodiazepines or other CNS Depressants

Concomitant use of opioids, including hydrocodone bitartrate and homatropine methylbromide, with benzodiazepines, or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Because of these risks, avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol (see **Precautions - Drug Interactions**).

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone. Because of similar pharmacologic properties, it is reasonable to expect similar risk with concomitant use of opioid cough medications and benzodiazepines, other CNS depressants, or alcohol.

Advise both patients and caregivers about the risks of respiratory depression and sedation if hydrocodone bitartrate and homatropine methylbromide is used with benzodiazepines, alcohol, or other CNS depressants (see **Precautions - Information for Patients**).

Hydrocodone can produce drug dependence of the morphine type and, therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration and it should be prescribed and administered with the same degree of caution appropriate to the use of other opioid drugs (See **DRUG ABUSE AND DEPENDENCE**).

Respiratory Depression

The use of hydrocodone bitartrate and homatropine syrup is not recommended for use in children less than 6 years of age because of the risk of fatal respiratory depression (see **ADVERSE REACTIONS-Respiratory Depression**). Hydrocodone bitartrate and homatropine methylbromide syrup produces dose-related respiratory depression by directly acting on brain stem respiratory centers. If respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride and other supportive measures when indicated.

Head Injury and Increased Intracranial Pressure

The respiratory depression properties of opioids and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, opioids produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions

The administration of hydrocodone bitartrate and homatropine methylbromide syrup or other opioids may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Pediatric Use

In pediatric patients, as well as adults, the respiratory center is sensitive to the depressant action of opioid cough suppressants in a dose-dependent manner. Caution should be exercised when administering hydrocodone bitartrate and homatropine methylbromide syrup to pediatric patients 6 years of age and older because of the potential for fatal respiratory depression. Overdose of concomitant

administration of hydrocodone bitartrate and homatropine methylbromide syrup with other respiratory depressants may increase the risk of respiratory depression in pediatric patients. Benefit to risk ratio should be carefully considered especially in pediatric population with respiratory embarrassment (e.g., croup) (see **PRECAUTIONS**).

PRECAUTIONS

General

Before prescribing medication to suppress or modify cough, it is important to ascertain that the underlying cause of cough is identified, that modification of cough does not increase the risk of clinical or physiological complications, and that appropriate therapy for the primary disease is provided.

Special Risk Patients

Hydrocodone bitartrate and homatropine methylbromide syrup should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal functions, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture, asthma, and narrow-angle glaucoma.

Information For Patients

Inform patients and caregivers that potentially fatal additive effects may occur if hydrocodone bitartrate and homatropine methylbromide is used with benzodiazepines or other CNS depressants, including alcohol. Because of this risk, patients should avoid concomitant use of hydrocodone bitartrate and homatropine methylbromide with benzodiazepines or other CNS depressants, including alcohol (see **Warnings, Precautions - Drug Interactions**).

Hydrocodone may produce marked drowsiness and impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using hydrocodone bitartrate and homatropine methylbromide syrup should be cautioned accordingly.

Patients should be advised to measure hydrocodone bitartrate and homatropine methylbromide syrup with an accurate measuring device. A household teaspoon is not an accurate measuring device and could lead to overdosage, especially when a half a teaspoon is measured. A pharmacist can recommend an appropriate measuring device and can provide instructions for measuring the correct dose. Keep out of the reach of children.

Drug Interactions

The use of benzodiazepines, opioids, antihistamines, antipsychotics, anti-anxiety agents, or other CNS depressants (including alcohol) concomitantly with hydrocodone bitartrate and homatropine methylbromide may cause an additive CNS depressant effect, profound sedation, respiratory depression, coma, and death and should be avoided (see **Warnings**).

The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies of hydrocodone bitartrate and homatropine methylbromide in animals to evaluate the carcinogenic and mutagenic potential and the effect on fertility have not been conducted.

Pregnancy

Teratogenic Effects: Pregnancy Category C

Animal reproduction studies have not been conducted with hydrocodone bitartrate and homatropine methylbromide. It is also not known whether hydrocodone bitartrate and homatropine methylbromide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Hydrocodone bitartrate and homatropine methylbromide should be given to a pregnant woman only if clearly needed.

Nonteratogenic Effects

Babies born to mothers who have been taking opioids regularly prior to delivery, will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting and fever. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose.

Labor and Delivery

As with all opioids, administration of hydrocodone bitartrate and homatropine methylbromide to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from hydrocodone bitartrate and homatropine methylbromide, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness of hydrocodone bitartrate and homatropine methylbromide in pediatric patients under six years of age have not been established. The use of hydrocodone bitartrate and homatropine methylbromide syrup in children less than 6 years of age has been associated with cases of fatal respiratory depression (see **ADVERSE REACTIONS - Respiratory Depression**). Hydrocodone bitartrate and homatropine methylbromide syrup should be used with caution in pediatric patients 6 years of age and older (see **WARNINGS - Pediatric Use**).

ADVERSE REACTIONS

To report SUSPECTED ADVERSE REACTIONS, contact Wockhardt USA, LLC at 1-800-445-4290 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Central Nervous System

Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, dizziness, psychic dependence, mood changes.

Gastrointestinal System

Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of hydrocodone bitartrate and homatropine methylbromide may produce constipation.

Genitourinary System

Ureteral spasm, spasm of vesicle sphincters and urinary retention have been reported with opiates.

Respiratory Depression

Hydrocodone bitartrate and homatropine methylbromide syrup may produce dose-related respiratory

depression by acting directly on brain stem respiratory centers (See **OVERDOSAGE**). Use of Hydrocodone bitartrate and homatropine methylbromide syrup in children less than 6 years of age has been associated with fatal respiratory depression. Overdose with Hydrocodone bitartrate and homatropine methylbromide syrup in children 6 years of age and older, in adolescents, and in adults has been associated with fatal respiratory depression.

Postmarketing events seen in children under 6 years of age include accidental overdose, bronchopneumonia, coma, cyanosis, death, death neonatal, dyspnea, pulmonary edema, respiratory arrest, and respiratory depression. Postmarketing events seen in patients older than 6 years of age include accidental overdose, cardio-respiratory arrest, death due to drug toxicity, non-accidental overdose, and overdose.

Dermatological

Skin rash, pruritus.

DRUG ABUSE AND DEPENDENCE

Hydrocodone bitartrate and homatropine methylbromide syrup is a Schedule II opioid. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of opioids; therefore, hydrocodone bitartrate and homatropine methylbromide syrup should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when hydrocodone bitartrate and homatropine methylbromide is used for a short time for the treatment of cough. Physical dependence, the condition in which continued administration of the drug is required to prevent the appearance of a withdrawal syndrome, assumes clinically significant proportions only after several weeks of continued oral opioid use, although some mild degree of physical dependence may develop after a few days of opioid therapy.

OVERDOSAGE

Signs and Symptoms

Serious overdosage with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur. The ingestion of very large amounts of hydrocodone bitartrate and homatropine methylbromide syrup may, in addition, result in acute homatropine intoxication.

Treatment

Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The opioid antagonist naloxone hydrochloride is a specific antidote for respiratory depression which may result from overdosage or unusual sensitivity to opioids including hydrocodone. Therefore, an appropriate dose of naloxone hydrochloride should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. For further information, see full prescribing information for naloxone hydrochloride. An antagonist should not be administered in the absence of clinically significant respiratory depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated. Gastric emptying may be useful in removing unabsorbed drug.

DOSAGE AND ADMINISTRATION

It is important that Hydrocodone Bitartrate and Homatropine Methylbromide Oral Solution is measured

with an accurate measuring device (see **PRECAUTIONS – Information for Patients**). A household teaspoon is not an accurate measuring device and could lead to overdosage, especially when a half a teaspoon is measured. It is strongly recommended that an accurate measuring device be used. A pharmacist can provide an appropriate measuring device and can provide instructions for measuring the correct dose.

Adults and adolescents 12 years of age and over: 5 mL (1 teaspoonful) of the syrup every 4 to 6 hours as needed; do not exceed 30 mL (6 teaspoonfuls) in 24 hours.

Children 6 to 11 years of age: 2.5 mL (½ teaspoonful) of the syrup every 4 to 6 hours as needed; do not exceed 15 mL (3 teaspoonfuls) in 24 hours.

HOW SUPPLIED

Hydrocodone bitartrate and homatropine methylbromide syrup is a red-colored, cherry-flavored syrup in 16 fl oz (473 mL) and gallon (3785 mL) bottles.

RECOMMENDED STORAGE

Store at 20°–25°C (68°–77°F) [see USP Controlled Room Temperature].

AVOID FREEZING

KEEP TIGHTLY CLOSED

Dispense in a tight, light-resistant container as defined in the USP.

Rx Only

Oral prescription where permitted by state law.

Product No.: 8455

Manufactured For:

Wockhardt USA, LLC

Parsippany, NJ 07054

Manufactured By:

Morton Grove Pharmaceuticals, Inc.

Morton Grove, IL 60053

A50-8455-16

REV. 12-16

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 accidently 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

Manufactured For:

Wockhardt USA, LLC

Parsippany, NJ 07054

Manufactured By:

Morton Grove Pharmaceuticals, Inc.

Morton Grove, IL 60053

28455A

Rev. 12-16

For more information, go to www.wockhardtusa.com or call Wockhardt USA, LLC at 1-800-346-6854.

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

PRINCIPAL DISPLAY PANEL mL Bottle Label

MGP

NDC 60432-455-16

HYDROCODONE AND HOMATROPINE SYRUP

(Hydrocodone Bitartrate and Homatropine Methylbromide Syrup)

CII

DO NOT USE IF INNER FOIL SEAL PRINTED "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

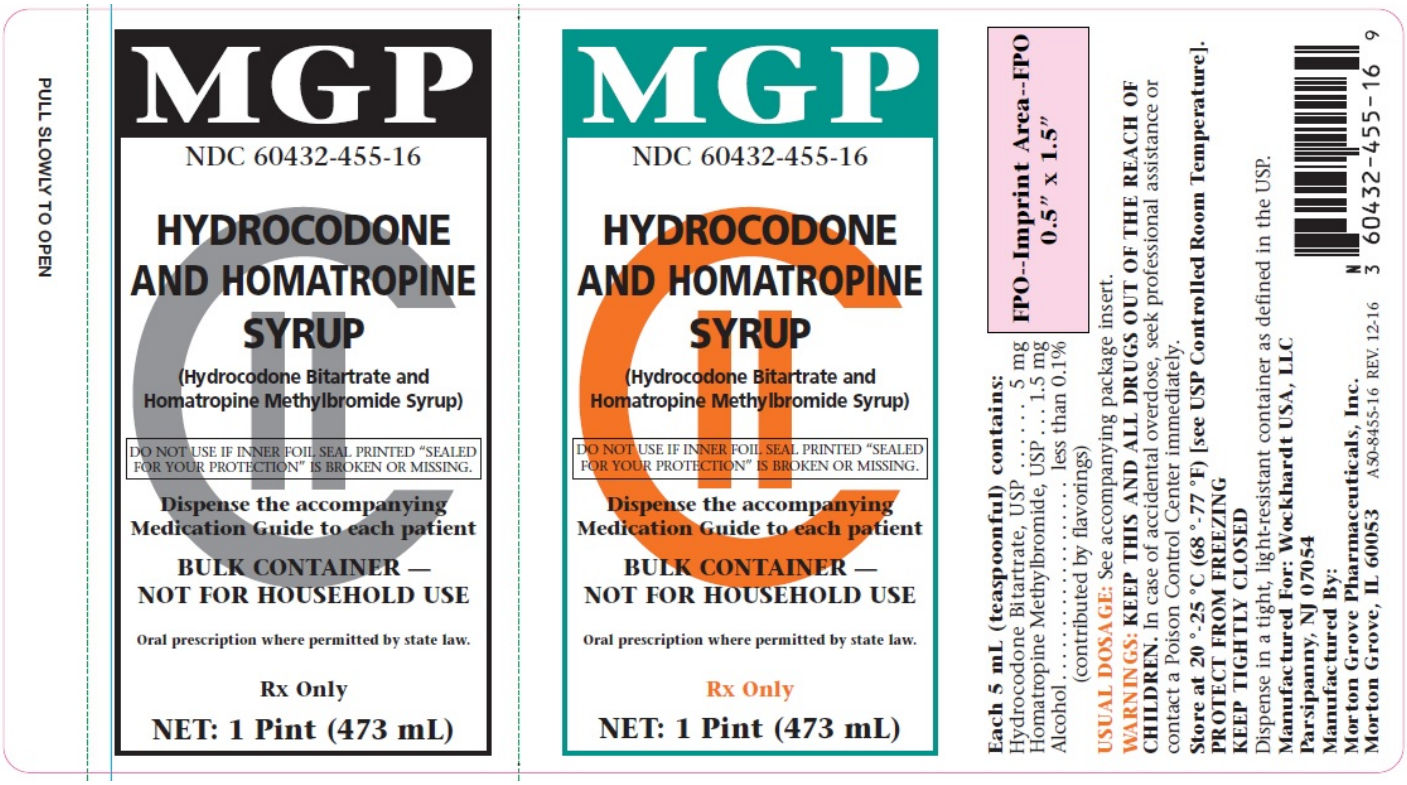
BULK CONTAINER —

NOT FOR HOUSEHOLD USE

Oral prescription where permitted by state law.

Rx Only

NET: 1 Pint (473 mL)



HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

hydrocodone bitartrate and homatropine methylbromide syrup

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60432-455
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCODONE BITARTRATE (UNII: NO70W886KK) (HYDROCODONE - UNII:6YKS4Y3WQ7)	HYDROCODONE BITARTRATE	5 mg in 5 mL
HOMATROPINE METHYLBROMIDE (UNII: 68JRS2HC1C) (METHYLHOMATROPINE - UNII:P97OGJ7L1L)	HOMATROPINE METHYLBROMIDE	1.5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITOL (UNII: 506T60A25R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
CARAMEL (UNII: T9D99G2B1R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics			
Color	RED	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60432-455-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/03/1983	
2	NDC:60432-455-28	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/03/1983	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088008	03/03/1983	

Labeler - Morton Grove Pharmaceuticals, Inc. (801897505)

Registrant - Morton Grove Pharmaceuticals, Inc. (801897505)

Establishment

Name	Address	ID/FEI	Business Operations
Morton Grove Pharmaceuticals, Inc.		801897505	ANALYSIS(60432-455) , LABEL(60432-455) , MANUFACTURE(60432-455) , PACK(60432-455)

Revised: 2/2017 Morton Grove Pharmaceuticals, Inc.