HYDROCODONE POLISTIREX AND CHLORPHENIRAMINE POLISTIREX EXTENDED-RELEASE- hydrocodone polistirex and chlorpheniramine polistirex suspension, extended release
Tris Pharma Inc

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension CII

(10 mg hydrocodone bitartrate and 8 mg chlorpheniramine maleate per 5 mL)

Rx only

BOXED WARNING

WARNING: RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS
Concomitant use of opioids with benzodiazepine or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death (see WARNINGS and PRECAUTIONS – Drug Interactions). Avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol.

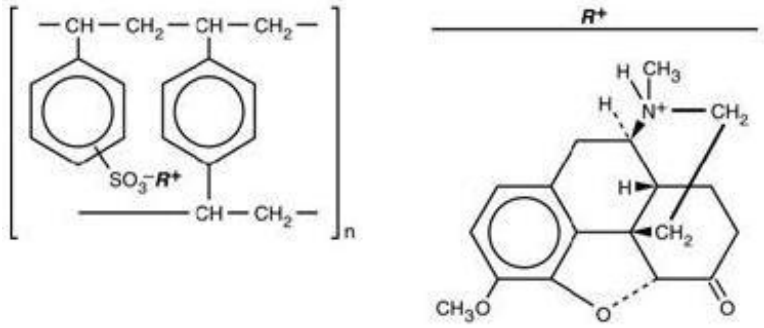
DESCRIPTION

Each 5 mL of Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release (ER) Suspension contains hydrocodone polistirex equivalent to 10 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg of chlorpheniramine maleate. Hydrocodone is a centrally-acting narcotic antitussive. Chlorpheniramine is an antihistamine.

Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension is for oral use only.

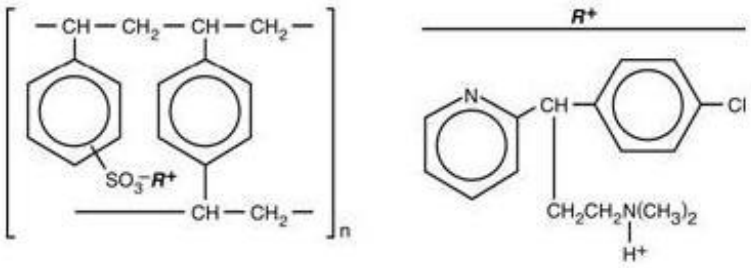
Hydrocodone Polistirex

Sulfonated styrene-divinylbenzene copolymer complex with 4,5α-epoxy-3-methoxy-17-methylmorphinan-6-one.



Chlorpheniramine Polistirex

Sulfonated styrene-divinylbenzene copolymer complex with 2-[p-chloro-α-[2-(dimethylamino)ethyl]-benzyl]pyridine.



Inactive Ingredients

Ascorbic acid, D&C Yellow No. 10, flavors, high fructose corn syrup, modified food starch, methylparaben, polysorbate 80, polyvinyl acetate, propylene glycol, propylparaben, purified water, sodium ascorbate, sodium metabisulfite, sodium polystyrene sulfonate, sucrose, triacetin, xanthan gum.

CLINICAL PHARMACOLOGY

Hydrocodone is a semisynthetic narcotic antitussive 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, and physical and psychological dependence.

Chlorpheniramine is an antihistamine drug (H1 receptor antagonist) that also possesses anticholinergic and sedative activity. It prevents released histamine from dilating capillaries and causing edema of the respiratory mucosa.

Hydrocodone release from Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension is controlled by an extended-release drug delivery system, which combines an ion-exchange polymer matrix with a diffusion rate-limiting permeable coating. Chlorpheniramine release is prolonged by use of an ion-exchange polymer system.

Following multiple dosing with Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension, hydrocodone mean (S.D.) peak plasma concentrations of 22.8 (5.9) ng/mL occurred at 3.4 hours. Chlorpheniramine mean (S.D.) peak plasma concentrations of 58.4 (14.7) ng/mL occurred at 6.3 hours following multiple dosing. Peak plasma levels obtained with an immediate-release syrup occurred at approximately 1.5 hours for hydrocodone and 2.8 hours for chlorpheniramine. The plasma half-lives of hydrocodone and chlorpheniramine have been reported to be approximately 4 and 16 hours, respectively.

INDICATIONS AND USAGE

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension is indicated for relief of cough and upper respiratory symptoms associated with allergy or a cold in adults and children 6 years of age and older.

CONTRAINDICATIONS

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension is contraindicated in patients with a known allergy or sensitivity to hydrocodone or chlorpheniramine.

The use of Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension is contraindicated in children less than 6 years of age due to the risk of fatal respiratory depression.

WARNINGS

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

Risk from Concomitant Use with Benzodiazepines or other CNS Depressants

Concomitant use of opioids, including Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension, 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 Polistirex and Chlorpheniramine Polistirex ER Suspension is used with benzodiazepines, alcohol, or other CNS depressants (see **PRECAUTIONS – Information for Patients**).

Respiratory Depression

As with all narcotics, Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension produces dose-related respiratory depression by directly acting on brain stem respiratory centers. Hydrocodone affects the center that controls respiratory rhythm and may produce irregular and periodic breathing. Caution should be exercised when Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension is used postoperatively and in patients with pulmonary disease, or whenever ventilatory function is depressed. If respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride and other supportive measures when indicated (see **OVERDOSAGE**).

Head Injury and Increased Intracranial Pressure

The respiratory depressant effects of narcotics 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, narcotics produce adverse reactions, which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions

The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Obstructive Bowel Disease

Chronic use of narcotics may result in obstructive bowel disease especially in patients with underlying intestinal motility disorder.

Pediatric Use

The use of Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension is contraindicated in children less than 6 years of age (see **CONTRAINDICATIONS**).

In pediatric patients, as well as adults, the respiratory center is sensitive to the depressant action of narcotic cough suppressants in a dose-dependent manner. Caution should be exercised when administering Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension to pediatric patients 6 years of age and older. Overdose or concomitant administration of Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension 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 patients with respiratory embarrassment (e.g., croup) (see **PRECAUTIONS**).

PRECAUTIONS

General

Caution is advised when prescribing this drug to patients with narrow-angle glaucoma, asthma, or prostatic hypertrophy.

Special Risk Patients

As with any narcotic agent, Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy, or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind.

Information for Patients

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Concomitant Use with Benzodiazepines or Other CNS Depressants

Inform patients and caregivers that potentially fatal additive effects may occur if Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension is used with benzodiazepines or other CNS depressants, including alcohol. Because of this risk, patients should avoid concomitant use of Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension with benzodiazepines or other CNS depressants, including alcohol (see **WARNINGS** and **PRECAUTIONS – Drug Interactions**).

Neurological Adverse Reactions

Advise patients that Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension 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. Advise patients to avoid driving or operating machinery during treatment with Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension.

Dosing Instructions

Advise patients not to dilute Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension with other fluids and not to mix with other drugs as this may alter the resin-binding and change the absorption rate, possibly increasing the toxicity.

Advise patients that Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension should be measured with an accurate measuring device. A household teaspoon is not an accurate measuring device and could lead to overdosage. A dosing cup is provided with the 4 oz (115 mL) packaged product. The dosing cup fills for 2.5 mL dose and for 5 mL dose. Instruct the patient to fill to the line that the dose has been prescribed. Do not fill over the dose prescribed. Rinse the measuring device or dosing cup with water after each use.

Shake well before using.

Keep out of the reach of children.

Alternatively, a pharmacist can recommend an appropriate measuring device and can provide instructions for measuring the correct dose.

Cough Reflex

Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when

Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension is used postoperatively, and in patients with pulmonary disease.

Drug Interactions

The use of benzodiazepines, opioids, antihistamines, antipsychotics, anti-anxiety agents, or other CNS depressants (including alcohol) concomitantly with Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension 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.

The concurrent use of other anticholinergics with hydrocodone may produce paralytic ileus.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity, and reproductive studies have not been conducted with Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension.

Pregnancy

Teratogenic Effects – Pregnancy Category C

Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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 narcotics, administration of Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension 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 Polistirex and Chlorpheniramine Polistirex ER Suspension, 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

The use of Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension is contraindicated in children less than 6 years of age (see **CONTRAINDICATIONS** and **ADVERSE REACTIONS, Respiratory, Thoracic and Mediastinal Disorders**).

Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension should be used with caution in pediatric patients 6 years of age and older (see **WARNINGS, Pediatric Use**).

Geriatric Use

Clinical studies of Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Gastrointestinal Disorders

Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension may produce constipation.

General Disorders and Administration Site Conditions

Death

Nervous System Disorders

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

Renal and Urinary Disorders

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

Respiratory, Thoracic and Mediastinal Disorders

Dryness of the pharynx, occasional tightness of the chest, and respiratory depression (see **CONTRAINDICATIONS**).

Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension may produce dose-related respiratory depression by acting directly on brain stem respiratory centers (see **OVERDOSAGE**). Use of Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension in children less than 6 years of age has been associated with fatal respiratory depression. Overdose with Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension in children 6 years of age and older, in adolescents, and in adults has been associated with fatal respiratory depression.

Skin and Subcutaneous Tissue Disorders

Rash, pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact Tris Pharma, Inc., at (732) 940-0358 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG ABUSE AND DEPENDENCE

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension is a Schedule II narcotic. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of narcotics; therefore, Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension 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 narcotic use, although some mild degree of physical dependence may develop after a few days of narcotic 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. Although miosis is characteristic of narcotic overdose, mydriasis may occur in terminal narcosis or severe hypoxia. In severe overdosage apnea, circulatory collapse, cardiac arrest and death may occur. The manifestations of chlorpheniramine overdosage may vary from central nervous system depression to stimulation.

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 narcotic antagonist naloxone hydrochloride is a specific antidote for respiratory depression which may result from overdosage or unusual sensitivity to narcotics including hydrocodone. Therefore, an appropriate dose of naloxone hydrochloride should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. Since the duration of action of hydrocodone in this formulation may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration. 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 Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension is measured with an accurate measuring device (see **PRECAUTIONS, Information for Patients**).

The dosing cup is provided with the 4 oz (115 mL) packaged product. The dosing cup fills for 2.5 mL dose and for 5 mL dose. Instruct the patient to fill to the line that the dose has been prescribed. Do not fill over the dose prescribed. Rinse the measuring cup with water after each use.

For prescriptions where a dosing device is not provided, a pharmacist can provide an appropriate measuring device and can provide instructions for measuring the correct dose. A household teaspoon is not an accurate measuring device and could lead to overdosage.

Each 5 mL of Hydrocodone Polistirex and Chlorpheniramine Polistirex ER Suspension contains hydrocodone polistirex equivalent to 10 mg hydrocodone bitartrate, and chlorpheniramine polistirex equivalent to 8 mg chlorpheniramine maleate. Shake well before using. Rinse the measuring device with water after each use.

Adults and Children 12 Years and Older

5 mL every 12 hours; do not exceed 10 mL in 24 hours.

Children 6 to 11 Years of Age

2.5 mL every 12 hours; do not exceed 5 mL in 24 hours.

This medicine is contraindicated in children under 6 years of age (see **CONTRAINDICATIONS**).

HOW SUPPLIED

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension, equivalent to 10 mg of hydrocodone bitartrate and 8 mg of chlorpheniramine maleate per 5 mL is a yellow viscous suspension available as:

NDC 27808-086-01 4 fl. oz. bottle containing 115 mL suspension. Each bottle is supplied with a dosing cup calibrated for measuring 2.5 mL and 5 mL doses.

NDC 27808-086-02 16 fl. oz. bottle containing 473 mL suspension.

Shake well. Dispense in a well-closed container.

Storage:

Store at 20° to 25°C (68° to 77°F); excursions permitted from 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Manufactured by:
Tris Pharma, Inc.
Monmouth Junction, NJ 08852
www.trispharma.com

MEDICATION GUIDE

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension CII
(hye" droe koe' done pol" i stye' rex and klor" fen ir' a mean pol" i stye' rex)

What is the most important information I should know about Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension?

• Taking Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension with benzodiazepines, or other central nervous system depressants, including alcohol can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.
• Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension can cause you to be drowsy. Avoid driving a car or operating machinery during treatment with Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension.
• Women who breastfeed should talk to their healthcare provider before taking Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension.
• Call your healthcare provider or get emergency medical help right away if anyone taking Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension has any of the symptoms below:

- increased sleepiness
- confusion
- difficulty breathing
- shallow breathing
- limpness
- your baby has difficulty breastfeeding

• Keep Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension 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 Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension, get emergency medical help right away.
• Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension can cause serious side effects, including death.

• Take Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension exactly as prescribed by your healthcare provider. If you take the wrong dose of Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension, you could overdose and die.
• Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension is not for children under 6 years of age.

What is Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension?

• Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension is a prescription medicine used to treat cough and upper respiratory symptoms you can have with allergies or a cold. Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension is for adults and children age 6 years and older. Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension contains 2 medicines, hydrocodone and chlorpheniramine. Hydrocodone is a narcotic cough suppressant. Chlorpheniramine is an antihistamine.
• **Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension is a federal controlled substance (CII) because it contains hydrocodone that can be abused or lead to dependence.** Keep Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension in a safe place to prevent misuse and abuse. Selling or giving away Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension may harm others, and is against the law. Tell your healthcare provider if you have abused or been dependent on alcohol, prescription medicines or street drugs.
• Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension is not for children under 6 years of age.

Who should not take Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension?

• **Do not** take Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension if you are allergic to any of the ingredients in Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension. See the end of this Medication Guide for a complete list of ingredients. You may have an increased risk of having an allergic reaction to Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension if you are allergic to certain other opioid medicines.
• **Do not** give Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension to a child under 6 years of age. It can cause breathing problems that can lead to death.

Before you take Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension, 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 glaucoma
- have prostate problems
- have problems with your urinary tract (urethral stricture)
- an to have surgery
- drink alcohol
- have kidney or liver problems
- have diabetes
- have thyroid problems, such as hypothyroidism
- Addison’s disease

• are pregnant or plan to become pregnant. It is not known if Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension will harm your unborn baby. You and your healthcare provider should decide if you should take Hydrocodone Polistirex and Chlorpheniramine

Polistirex Extended-Release Suspension while you are pregnant.
• are breastfeeding or plan to breastfeed. It is not known if Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension passes into your breast milk. You and your healthcare provider should decide if you will take Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension 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 Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension with certain other medicines can cause side effects or affect how well Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

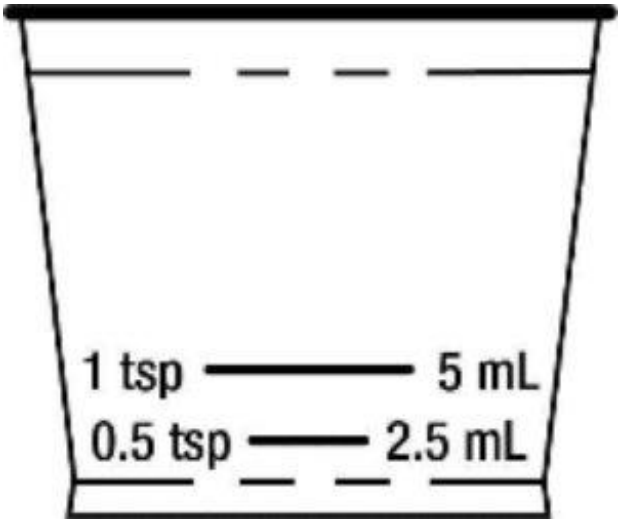
Especially tell your healthcare provider if you:
• take pain medicines such as narcotics
• take cold or allergy medicines that contain antihistamines or cough suppressants
• take medicines for mental illness (anti-psychotics, anti-anxiety)
• drink alcohol
• take medicines for depression, including monoamine oxidase inhibitors (MAOIs) and tricyclics
• take medicines for stomach or intestine problems

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

How should I take Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension?

• Take Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension exactly as your healthcare provider tells you to take it.
• Your healthcare provider will tell you how much Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension to take and when to take it. Do not change your dose without talking to your healthcare provider.
• Shake Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension well before each use.
• Do not mix Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension with other liquids or medicines. Mixing may change how Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension works.
• Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension can be taken with or without food.
• **Only measure Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension with the dosing cup that comes with your prescription.** If you do not have a dosing cup for your medicine, ask your pharmacist to give you a measuring device to help you measure the correct amount of Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension. **Do not use a household teaspoon to measure your medicine. You may accidently take too much.**

- The dosing cup is calibrated for measuring 2.5 mL and 5 mL dosages. Find the marked line for the dose you are taking.
- Fill the cup so the medicine is leveled to the dose that has been prescribed. **Do not fill** over the dosage line.
- Rinse the measuring cup with water after each use.



• **If you take too much Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension, call your healthcare provider or go to the nearest hospital emergency room right away.**

What are the possible side effects of Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension?

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension may cause serious side effects, including:

• **See "What is the most important information I should know about Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension?"**

• **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.

• **Increased intracranial pressure.**

• **Physical dependence or abuse.** Take Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension exactly as your healthcare provider tells you to take it. Stopping Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension suddenly can cause withdrawal symptoms.

• **Bowel problems including constipation or stomach pain.**

The most common side effects of Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension include:

• **sleepiness**
• **confusion**
• **nausea and vomiting**
• **difficulty urinating**
• **trouble breathing**

These are not all the possible side effects of Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension.

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 Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension?

• Store Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension at room temperature between 68°F to 77°F (20°C to 25°C).

• Safely throw away medicine that is out of date or no longer needed.

• **Keep Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension and all medicines out of the reach of children.**

General information about the safe and effective use of Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension for a condition for which it was not prescribed. Do not give Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension 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 Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension that is written for health professionals.

What are the ingredients in Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension?

Active Ingredient: hydrocodone polistirex and chlorpheniramine polistirex

Inactive Ingredients: Ascorbic acid, D&C Yellow No. 10, flavors, high fructose corn syrup, modified food starch, methylparaben, polysorbate 80, polyvinyl acetate, propylene glycol, propylparaben, purified water, sodium ascorbate, sodium metabisulfite, sodium polystyrene sulfonate, sucrose, triacetin, xanthan gum.

Manufactured by:

Tris Pharma, Inc.

Monmouth Junction, NJ 08852

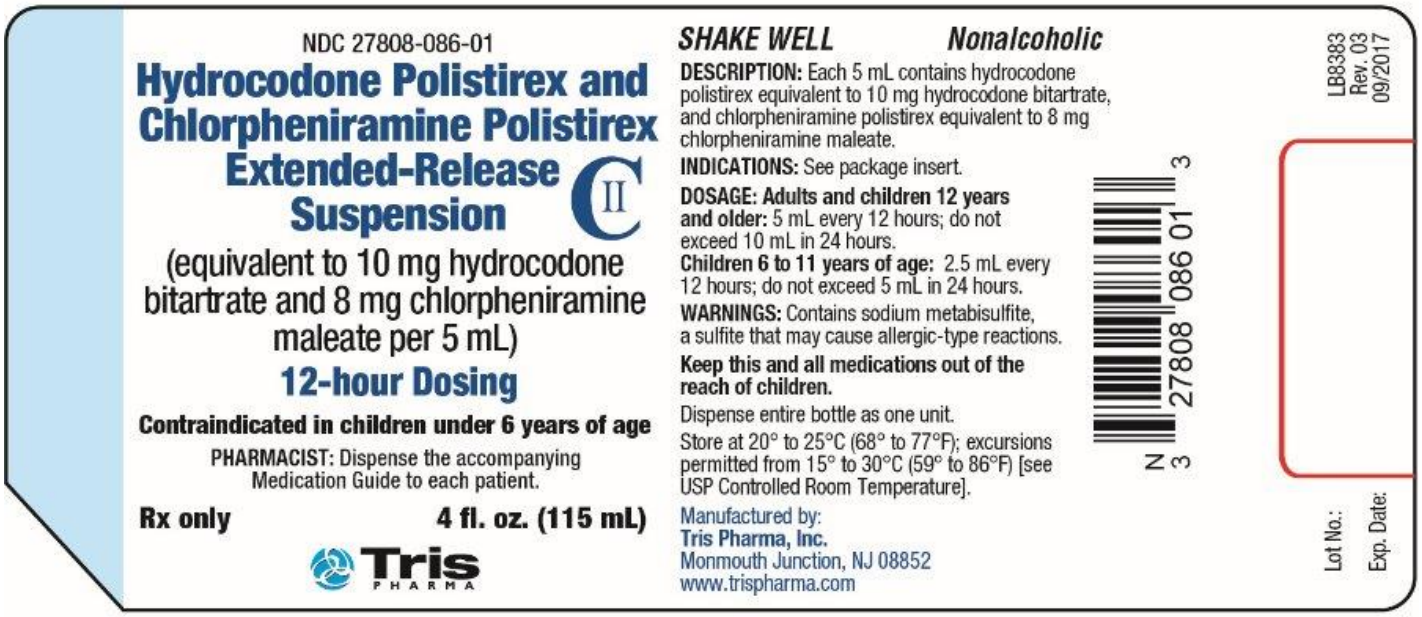
For more information about Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Suspension, contact Tris Pharma Inc., at 732-940-0358 or go to www.trispharma.com.

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

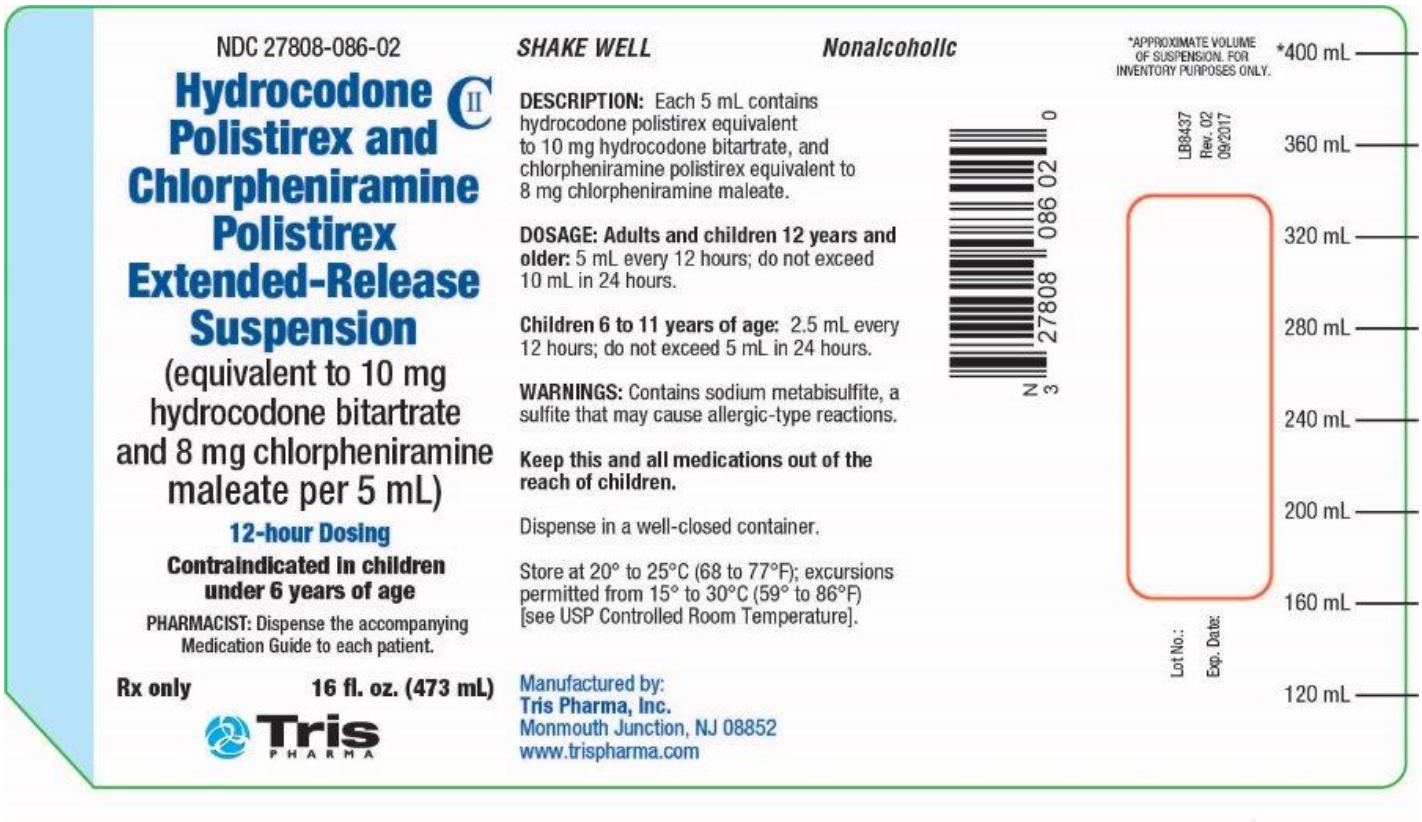
Issued: 09/2017

PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL



PRINCIPAL DISPLAY PANEL



HYDROCODONE POLISTIREX AND CHLORPHENIRAMINE POLISTIREX EXTENDED-RELEASE

hydrocodone polistirex and chlorpheniramine polistirex suspension, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:27808-086
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCODONE BITARTRATE (UNII: NO70W886KK) (HYDROCODONE - UNII:6YKS4Y3WQ7)	HYDROCODONE BITARTRATE	10 mg in 5 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	8 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ACETATE (UNII: 32K497ZK2U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM ASCORBATE (UNII: S033EH8359)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
SUCROSE (UNII: C151H8M554)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	YELLOW	**Score**	
Shape		**Size**	
Flavor	PEACH, PINEAPPLE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27808-086-01	1 in 1 CARTON	03/06/2015	
1		115 mL in 1 BOTTLE, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:27808-086-02	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/06/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091632	03/06/2015	

Labeler - Tris Pharma Inc (947472119)

Revised: 10/2017 Tris Pharma Inc