**INDICATIONS AND USAGE**

TussiCaps® extended-release capsules are 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**

TussiCaps® extended-release capsules are contraindicated in patients with a known allergy or sensitivity to hydrocodone or chlorpheniramine.

**WARNINGS**

**Respiratory Depression** – As with all narcotics, TussiCaps® extended-release capsules produce 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 TussiCaps® extended-release capsules are used postoperatively and in patients with pulmonary disease, or whenever respiratory 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 depressive 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 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.

**Pediatric Use** – The use of TussiCaps® extended-release capsules is contraindicated in children less than 6 years of age due to the risk of fatal respiratory depression.

**PREGNANCY**

The concurrent use of other anticholinergics with hydrocodone may produce additive anticholinergic effects.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Carcinogenicity, mutagenicity, and reproductive studies have not been conducted with TussiCaps® extended-release capsules.
Labor and Delivery

As with all narcotics, administration of TussiCaps® extended-release capsules 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 of developing adverse reactions in nursing infants from TussiCaps® extended-release capsules, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

The use of TussiCaps® extended-release capsules are contraindicated in children less than 6 years of age (see CONTRAINDICATIONS and ADVERSE REACTIONS, Respiratory, Thoracic and Mediastinal Disorders). TussiCaps® extended-release capsules 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 extended-release 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 dosage 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 TussiCaps® extended-release capsules may produce constipation. General Disorders and Administration Site Conditions

Dryness of the pharynx, occasional tightness of the chest, and respiratory depression (see CONTRAINDICATIONS). TussiCaps® extended-release capsules may produce dose-related respiratory depression by acting directly on brain stem respiratory centers (see OVERTOXICITY). Use of TussiCaps® in children less than 6 years of age has been associated with fatal respiratory depression. Overdose with TussiCaps® extended-release capsules 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.

DRUG ABUSE AND DEPENDENCE

TussiCaps® extended-release capsules are Schedule II narcotics. Psychotic reactions, severe psychological and/or physical dependence, and tolerance may develop upon repeated administration of narcotics; therefore, TussiCaps® extended-release capsules should be prescribed and administered with caution. However, psychotic dependence is unlikely to develop when TussiCaps® extended-release capsules are 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, may also occur, and may develop after several weeks of therapy in patients being treated with higher doses for severe chronic cough. Physical dependence may develop after a few days of narcotic therapy.

OVERTOXICITY

Signs and Symptoms – Overdose 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. However, miosis is characteristic of narcotic overdose, mydriasis may occur in terminal narcosis or severe hypoxia. In severe overdosage, apraxia, circulatory collapse, cardiac arrest and death may occur. The manifestations of chlorpheniramine overdose may vary from cataract renal system depression to stimulation. Treatment – Primary attention should be given to the readjustment 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, preferrably 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 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.

DOSEAGE AND ADMINISTRATION

Adults and Children 12 Years of Age and Older

One (1) full-strength TussiCaps® extended-release capsule (Hydrocodone bitartrate equivalent to 10 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg of chlorpheniramine maleate) every 6 hours; do not exceed 2 capsules in 24 hours.

Children 6 to 11 Years of Age

One (1) half-strength TussiCaps® extended-release capsule (Hydrocodone bitartrate equivalent to 5 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 4 mg of chlorpheniramine maleate) every 6 hours; do not exceed 2 capsules in 24 hours.

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