

Training, Lay Rescuers Key to Better CPR Results

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Southeast Bureau

Bystander-initiated cardiopulmonary resuscitation saves lives but occurs far too infrequently and is often provided inadequately, according to a new scientific statement from the American Heart Association.

The statement calls for a concerted effort by health care providers, policy makers, and community leaders to provide ed-

ucation and training to improve the rate and quality of bystander CPR.

"CPR is an inexpensive and readily available technique that can save lives. Therefore, the number of people trained in CPR must increase, and the quality of CPR provided must improve," wrote Dr. Benjamin S. Abella, lead author of the statement, and his colleagues (*Circulation* 2008;117;704-9).

Although it has been shown that high-quality CPR provided by bystanders can

improve the rates of survival to hospital discharge, in many communities only 15%-30% of victims receive bystander CPR before emergency medical services personnel arrive. With arrival times often occurring after 7-8 minutes, and a drop in survival rates of 7%-10% for each minute without CPR, the lack of bystander-initiated CPR can have a dramatic impact on patient outcome.

"In communities where widespread CPR training has been provided, survival

rates from witnessed sudden cardiac arrest associated with [ventricular fibrillation] have been reportedly as high as 49% to 74% ... unfortunately, on average, about 6% of out-of-hospital sudden cardiac arrest victims survive to hospital discharge in the United States," Dr. Abella, clinical research director for the Center for Resuscitation Science at the University of Pennsylvania, Philadelphia, said in a press statement.

Study findings have shown that even when CPR by a bystander and CPR by trained health care professionals are provided, they are too often provided inadequately, with chest compressions that are too shallow or interrupted too often, and with excessive rates of rescue breathing. The authors provide a number of recommendations to improve the rate and quality of bystander CPR, including:

► **Broadening CPR training.** New approaches in training are needed to reach a larger public audience. A 22-minute, self-instructional program available through the AHA is an example of a tool that can be used outside the classroom. The statement also calls for community and corporate programs to encourage CPR education, and suggests that training be provided in high schools as a prerequisite for graduation and in hospitals for families of patients at risk for sudden cardiac arrest.

► **Addressing common barriers to lay rescuer action.** Bystanders are often reluctant to perform CPR out of fear of disease transmission, fear of legal liability, or as a result of the complexity of guidelines and instructional materials (which hampers both learning and delivery of bystander CPR). Thus, in addition to education about the value of quick action for saving lives, the public should be better informed about the very low risk of disease transmission (there have been no reported cases of HIV transmission or hepatitis via CPR, for example) and the availability of mouth-to-mouth barrier devices and gloves, which should be mandated wherever an automatic external defibrillator (AED) is stationed. Information about Good Samaritan laws that protect bystanders from liability should be included in CPR training and posted prominently near AED stations.

► **Improving lay rescuer and emergency medical services programs.** These programs can be upgraded by providing a process for continuous quality improvement. Reviews of resuscitation efforts and quality of CPR provided by bystanders and dispatchers are needed, as is monitoring (by health care systems that provide CPR services) of the quality of CPR provided during resuscitation efforts.

The AHA also suggests Internet-based CPR education and certification programs be developed, and that research be done to identify the best educational methods for delivering CPR training, the optimal target populations for CPR education, the value of dispatch-assisted CPR in a variety of communities, and the public perceptions that serve as barriers to CPR training and administration. ■

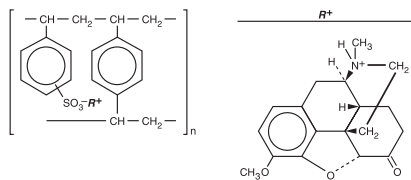
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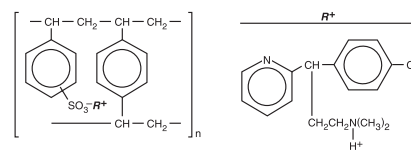
Penkinetic®
(hydrocodone polistirex and chlorpheniramine polistirex)
Extended-Release Suspension

DESCRIPTION: Each teaspoonful (5 mL) of TUSSIONEX Penkinetic Extended-Release Suspension contains hydrocodone polistirex equivalent to 10 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg of chlorpheniramine maleate. TUSSIONEX Penkinetic Extended-Release Suspension provides up to 12-hour relief per dose. Hydrocodone is a centrally-acting narcotic antitussive. Chlorpheniramine is an antihistamine. TUSSIONEX Penkinetic Extended-Release 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, ethylcellulose, FD&C Yellow No. 6, flavin, high fructose corn syrup, methylparaben, polyethylene glycol 3350, polysorbate 80, pregelatinized starch, propylene glycol, propylparaben, purified water, sucrose, vegetable oil, 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 TUSSIONEX Penkinetic Extended-Release Suspension is controlled by the Penkinetic System, 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 TUSSIONEX Penkinetic Extended-Release 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: TUSSIONEX Penkinetic 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: TUSSIONEX Penkinetic Extended-Release Suspension is contraindicated in patients with a known allergy or sensitivity to hydrocodone or chlorpheniramine.

The use of TUSSIONEX Penkinetic Extended-Release Suspension is contraindicated in children less than 6 years of age.

WARNINGS: Respiratory Depression: As with all narcotics, TUSSIONEX Penkinetic Extended-Release 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 TUSSIONEX Penkinetic Extended-Release 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: 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. 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, TUSSIONEX Penkinetic Extended-Release 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: As with all narcotics, TUSSIONEX Penkinetic Extended-Release 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; patients should be cautioned accordingly. TUSSIONEX Penkinetic Extended-Release Suspension must not be diluted with fluids or mixed with other drugs as this may alter the resin-binding and change the absorption rate, possibly increasing the toxicity.

Keep out of the reach of children.

Cough Reflex: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when TUSSIONEX Penkinetic Extended-Release Suspension is used postoperatively, and in patients with pulmonary disease.

Drug Interactions: Patients receiving narcotics, antihistamines, antipsychotics, anti-anxiety agents, or other CNS depressants (including alcohol) concomitantly with TUSSIONEX Penkinetic Extended-Release Suspension may exhibit an additive CNS depression. When combined therapy is contemplated, the dose of one or both agents should be reduced.

Rx Only

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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 TUSSIONEX Penkinetic Extended-Release 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. TUSSIONEX Penkinetic Extended-Release 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 TUSSIONEX Penkinetic Extended-Release 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 TUSSIONEX Penkinetic Extended-Release 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: Safety and effectiveness of TUSSIONEX Penkinetic Extended-Release Suspension in pediatric patients under six have not been established (see WARNINGS).

Geriatric Use: Clinical studies of TUSSIONEX 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: Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, euphoria, dizziness, psychic dependence, mood changes.

Dermatologic System: Rash, pruritus.

Gastrointestinal System: Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of TUSSIONEX Penkinetic Extended-Release Suspension may produce constipation.

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

Respiratory Depression: TUSSIONEX Penkinetic Extended-Release Suspension may produce dose-related respiratory depression by acting directly on brain stem respiratory centers (see OVERDOSAGE).

Respiratory System: Dryness of the pharynx, occasional tightness of the chest.

DRUG ABUSE AND DEPENDENCE: TUSSIONEX Penkinetic Extended-Release Suspension is a Schedule III narcotic. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of narcotics; therefore, TUSSIONEX Penkinetic Extended-Release Suspension should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when TUSSIONEX Penkinetic Extended-Release 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 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. Although miosis is characteristic of narcotic overdose, mydriasis may occur in terminal narcosis or severe hypoxia. In severe overdose apnea, circulatory collapse, cardiac arrest and death may occur. The manifestations of chlorpheniramine overdose 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 overdose 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

Shake well before using.

Adults and Adolescents ≥ 13 Years of Age
5 mL (1 teaspoonful) every 12 hours; do not exceed 10 mL (2 teaspoonfuls) in 24 hours.

Children 6-12 Years of Age
2.5 mL (1/2 teaspoonful) every 12 hours; do not exceed 5 mL (1 teaspoonful) in 24 hours.

It is important that TUSSIONEX be measured accurately. A household teaspoonful is not an accurate measuring device and could lead to overdose, especially when half a teaspoon is to be 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. Please ask a pharmacist for advice.

This medicine is not intended for children under 6 years of age (see CONTRAINDICATIONS).

HOW SUPPLIED: TUSSIONEX Penkinetic (hydrocodone polistirex and chlorpheniramine polistirex) Extended-Release Suspension is a gold-colored suspension.

NDC 53014-548-67 473 mL bottle

For Medical Information

Contact: Medical Affairs Department
Phone: (866) 822-0068
Fax: (770) 970-8859

Storage:

Shake well. Dispense in a well-closed container.

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

TUSSIONEX Penkinetic Extended-Release Suspension

Manufactured for:
UCB, Inc.
Smyrna, GA 30080



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