

Many Hispanics Lack Usual Health Care Provider

BY ALICIA AULT

Associate Editor, Practice Trends

WASHINGTON — Hispanics may place significant stress on the health care system in the future, as they are projected to be the largest segment of the population by 2050 but are less likely to have a usual source of care and have less knowledge about chronic disease, according to new data from the Pew Hispanic Center and the U.S. Census Bureau.

The Hispanic population will triple from 2008 to 2050, rising from 47 million today to 133 million in 4 decades. By 2050, Hispanics will make up 30% (131 million) of the nation's total population of an estimated 439 million, according to the Census Bureau.

And, as the nation ages overall, the number of Hispanics who are aged 65 years and older also will rise. By 2050, 88 million people will be older than 65 years old, according to the Census Bureau.

Currently, there are some 45 million Hispanics in the United States, 30 million of whom are adults, according to a new report by the Pew Hispanic Center, "Hispanics and Health Care in the United States: Access, Information and Knowledge." The Pew Hispanic Center, in conjunction with the Robert Wood Johnson Foundation, conducted a national telephone survey in mid to late 2007. Overall, about 4,000 Hispanic individuals completed the survey.

Survey data showed that Hispanics generally tend to be young and healthy, but have a high prevalence of obesity and a predisposition to diabetes, indicating a potential future crisis, said Susan Minushkin, deputy director of the Pew Hispanic Center, in a briefing with reporters. The Centers for Disease Control and Prevention has estimated that 10% of Hispanics have diabetes, 20% have hypertension, 40% are overweight, and 27% are obese, she said.

Therefore, it is worrisome that 27% of Hispanics—approximately 8 million adults—lacked a usual health care provider, Ms. Minushkin said. Only 62% of Hispanics without a usual provider had a blood pressure check in the last 2 years, compared with 86% of those who have a provider, the Pew Center found. Only 67% of those lacking a usual provider had a blood sugar test in the last 2 years, compared with 90% of those with a provider.

Diabetes knowledge was inconsistent, even among those diagnosed with the disease, the Pew Center found. Of diagnosed diabetics, 27% answered at least three of eight questions about the disease incorrectly, for instance. Overall, Hispanic women were more likely to give correct answers, as were middle-aged Hispanics of both sexes. Immigrants had the least amount of knowledge.

Those who did not have a usual health care provider were more likely to be young (aged 18-29 years), to lack a high school diploma, and to be uninsured. They also were more likely to be predominantly Spanish-speaking and to be foreign-born but not yet legal permanent residents. However, 45% of those who did not have a usual provider had health insurance.

The primary reason—given by 41% of respondents—for not having a usual health care provider was that they were seldom or never sick. Another 13% said they treat themselves or don't use a physician, 11% said the cost of care was prohibitive, 2% said they didn't know where to go for care, and 1% said they couldn't find a provider who spoke their language.

Though 78% rated the quality of their care as good or excellent, some 25% said the care they received was poor, which they blamed on their ethnicity or their English-speaking skills or accent.

More than two-thirds of respondents (71%) said they received information about health from a physician or other medical professional, but 83% said they received it from the media. "I can't comment on whether the information they are getting is good or bad," said Ms. Minushkin, adding that the Pew Center did not ask what types of media were being cited.

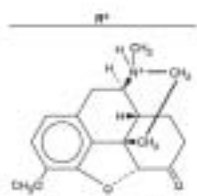
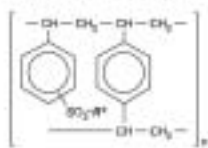
But, she added, "those who do get information from the media make changes in their behavior." About 40%-64% said the information affected decisions on how to treat an illness, led them to ask a physician a new question, or changed the way they thought about diet or exercise.

The National Hispanic Medical Association has joined the call for the establishment of medical homes that would provide patient-centered, coordinated care, Dr. Elena Rios, president and CEO of the NHMA, said at the briefing. ■

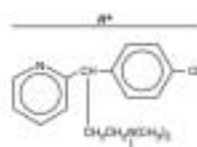
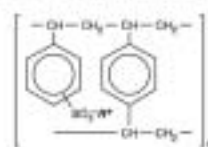
Tussionex[®] Pennkinetic[®] (hydrocodone polistirex and chlorpheniramine polistirex) Extended-Release Suspension

DESCRIPTION: Each teaspoonful (5 mL) of TUSSIONEX Pennkinetic Extended-Release Suspension contains hydrocodone polistirex equivalent to 10 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg of chlorpheniramine bitartrate. TUSSIONEX Pennkinetic Extended-Release Suspension provides up to 12-hour relief per dose. Hydrocodone is a centrally-acting narcotic analgesic. Chlorpheniramine is an antihistamine. TUSSIONEX Pennkinetic Extended-Release Suspension is for oral use only.

Hydrocodone Polistirex: Sulfonated styrene-divinylbenzene copolymer complex with 4,5-epoxy-3-methyl-17-morpholinopropylamine.



Chlorpheniramine Polistirex: Sulfonated styrene-divinylbenzene copolymer complex with 2-[p-chloro-4-(2-dimethylaminoethyl)butyl]pyridine.



Inactive Ingredients: Ascorbic acid, D&C Yellow No. 10, ethylcellulose, FD&C Yellow No. 6, Inco, high fructose corn syrup, methylcellulose, polyethylene glycol 3350, polyethylene glycol 400, pregelatinized starch, propylene glycol, propylparaben, purified water, sucrose, vegetable oil, xanthan gum.

CLINICAL PHARMACOLOGY: Hydrocodone is a semisynthetic narcotic analgesic and anesthetic 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 opiate derivatives, will depress respiration. The effects of hydrocodone is therapeutic doses on the cardiovascular system are insignificant. Hydrocodone can produce nausea, euphoria, and physical and psychological dependence.

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

Hydrocodone release from TUSSIONEX Pennkinetic Extended-Release Suspension is controlled by the Pennkinetic 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 Pennkinetic Extended-Release Suspension, hydrocodone mean (S.D.) peak plasma concentrations of 32.8 (5.0) ng/mL, occurred at 3.4 hours. Chlorpheniramine mean (S.D.) peak plasma concentrations of 58.4 (14.7) ng/mL, occurred at 8.3 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 10 hours, respectively.

INDICATIONS AND USAGE: TUSSIONEX Pennkinetic 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 Pennkinetic Extended-Release Suspension is contraindicated in patients with a known allergy or sensitivity to hydrocodone or chlorpheniramine.

The use of TUSSIONEX Pennkinetic Extended-Release Suspension is contraindicated in children less than 6 years of age due to the risk of fatal respiratory depression.

WARNINGS: Respiratory Depression: As with all narcotics, TUSSIONEX Pennkinetic 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 Pennkinetic 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: The use of TUSSIONEX Pennkinetic Extended-Release 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 TUSSIONEX Pennkinetic Extended-Release Suspension to pediatric patients 6 years of age and older. Overdose or concomitant administration of TUSSIONEX Pennkinetic Extended-Release 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, TUSSIONEX Pennkinetic 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 Pennkinetic 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 Pennkinetic 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.

Patients should be advised to measure TUSSIONEX Pennkinetic Extended-Release Suspension with an accurate measuring device. A household teaspoon is not an accurate measuring device and could lead to overdose, 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.

Shake well before using.

Keep out of the reach of children.

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

Rx Only
NDC 012500 1E
TU1186-0000 1E

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

The use of MAOI 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 anticholinergic effects.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenicity, mutagenicity, and reproductive studies have not been conducted with TUSSIONEX Pennkinetic Extended-Release Suspension.

Pregnancy, Teratogenic Effects - Pregnancy Category C

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

Neuroleptic Effects: Sabin born to mothers who have been taking opiates 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 opiate use or dose.

Labor and Delivery: As with all narcotics, administration of TUSSIONEX Pennkinetic 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 Pennkinetic Extended-Release Suspension, a decision should be made whether to discontinue a nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: The use of TUSSIONEX Pennkinetic Extended-Release Suspension is contraindicated in children less than 6 years of age (see CONTRAINDICATIONS and ADVERSE REACTIONS, Respiratory, Thoracic and Medicinal Disorders).

TUSSIONEX Pennkinetic Extended-Release Suspension should be used with caution in pediatric patients 6 years of age and older (see WARNINGS, Pediatric Use).

Geriatric Use: Clinical studies of TUSSIONEX did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently than 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 TUSSIONEX Pennkinetic Extended-Release Suspension may produce constipation.

General Disorders and Administration Site Conditions: Drowsiness.

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

Respiratory, Thoracic and Medicinal Disorders: Dryness of the pharynx, occasional tightness of the chest, and respiratory depression (see CONTRAINDICATIONS).

TUSSIONEX Pennkinetic Extended-Release Suspension may produce dose-related respiratory depression by acting directly on brain stem respiratory centers (see OVERDOSAGE). Use of TUSSIONEX Pennkinetic Extended-Release Suspension in children less than 6 years of age has been associated with fatal respiratory depression. Overdose with TUSSIONEX Pennkinetic Extended-Release 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.

DRUG ABUSE AND DEPENDENCE: TUSSIONEX Pennkinetic Extended-Release Suspension is a Schedule III narcotic. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of narcotics; therefore, TUSSIONEX Pennkinetic Extended-Release Suspension should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when TUSSIONEX Pennkinetic 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, occurs in 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 nausea is characteristic of narcotic overdose, vomiting may occur in terminal stages or severe hypoxia. In severe overdosage apnea, respiratory 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 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 antidote 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.

DOSE AND ADMINISTRATION: It is important that TUSSIONEX be measured with an accurate measuring device (see PRECAUTIONS, Information for Patients). A household teaspoon 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 use provide instructions for measuring the correct dose.

Shake well before using.

Adults and Children 12 Years and Older: 5 mL (1 teaspoonful) every 12 hours; do not exceed 10 mL (2 teaspoonfuls) in 24 hours.

Children 6-11 Years of Age: 2.5 mL (1/2 teaspoonful) every 12 hours; do not exceed 5 mL (1 teaspoonful) in 24 hours. This medicine is contraindicated in children under 6 years of age (see CONTRAINDICATIONS).

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

NDC 52814-548-67 473 mL 308B

For Medical Information: Contact: Medical Affairs Department / Phone: (800) 822-0088 / Fax: (770) 370-5833

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 Pennkinetic Extended-Release Suspension

Manufactured for:

UCB, Inc.

Smyrna, GA 30080



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