CDC Report Provides Snapshot of U.S. Health

BY MARY ANN MOON

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he use of medical technology has grown dramatically over the last decade, according to the federal government's annual health report.

That's just one finding in the massive "Health, United States, 2009," a snapshot of Americans' health, which the Centers for Disease Control and Prevention compiles yearly as "an essential step in mak-

BRIEF SUMMARY - Consult full prescribing information before use. TussiCaps®

Ш (Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-Release Capsules

Rx only

CONTRAINDICATIONS

TussiCaps[®] extended-release capsules are contraindicat-ed in patients with a known allergy or sensitivity to hydrocodone or chlorpheniramine.

The use of TussiCaps[®] extended-release capsules are contraindicated in children less than 6 years of age due to the risk of fatal respiratory depression.

WARNINGS

WARNINGS Respiratory Depression – As with all narcotics, TussiCaps[®] extended-release capsules produce dose-related respira-tory depression by directly acting on brain stem respirato-ry centers. Hydrocodone affects the center that controls respiratory rhythm, and may produce irregular and period-ic breathing. Caution should be exercised when TussiCaps[®] extended-release capsules are used postop-eratively and in patients with pulmonary disease, or when-ever 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 pressure. Every theorem on preventing increase in intracranial pressure. sure. Furthermore, narcotics produce adverse reactions, which may obscure the clinical course of patients with head

Acute Abdominal Conditions - The administration of nar cotics 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 TussiCaps[®] extended-release capsules are contraindicated in children less than 6 years of age (see CONTRAINDICATIONS).

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 TussiCaps[®] extended-release capsules to pediatric patients 6 years of age and older. Overdose or concomi-tant administration of TussiCaps[®] extended-release cap-sules 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 embar-rassment (e.g., croup) (see **PRECAUTIONS**).

PRECAUTIONS

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

Trophy. Special Risk Patients – As with any narcotic agent, TussiCaps[®] extended-release capsules 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

Information for Patients As with all narcotics, TussiCaps[®] extended-release cap-sules may produce marked drowsiness and impair the mental and/or physical abilities required for the perform-ance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly. TussiCaps[®] extended-release capsules 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 TussiCaps[®] extended-release capsules are used postoperatively, and in patients with pulmonary disease. Drug Interactions

Patients receiving narcotics, antihistamines, antipsy-chotics, antianxiety agents, or other CNS depressants

ing sound health policy and setting research and program priorities.'

This year's edition, the 33rd, includes a special section on medical technology, which includes procedures, tests, drugs, devices, and support systems such as computerized records. The principal findings in this section include:

► The use of MRI, CT, and PET imaging soared during the past decade. The number of such imaging studies either or-

(including alcohol) concomitantly with TussiCaps[®] extend-ed-release capsules may exhibit an additive CNS depres-sion. When combined therapy is contemplated, the dose of one or both agents should be reduced.

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 TussiCaps[®] extended release capsules. 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 ade-quate and well-controlled studies in pregnant women. TussiCaps[®] extended-release capsules should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects - Babies born to mothers who Nonteratogenic Erfects – Bables born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irri-tability and excessive crying, tremors, hyperactive reflex-es, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever. The intensity of the syn-drome does not always correlate with the duration of maternal opioid use or dose.

Labor and Delivery

As with all narcotics, administration of TussiCaps[®] extend-ed-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 for serious adverse reactions in nursing infants from TussiCaps[®] extended-release capsules, 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 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

Geriatric Use Clinical studies of hydrocodone polistirex and chlorpheni-ramine polistirex extended-release did not include suffi-cient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differ-ences in responses between the elderly and younger patients. In general, does eselection 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 con-comitant disease or other drug therapy. This drug is known to be substantially excreted hy the kid-

This drug is known to be substantially excreted by the kid-ney, 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

Nervous System Disorders

Sedation, drowsiness, mental clouding, lethargy, impair-ment 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**). TussiCaps® extended-release capsules may produce dered or provided by physician offices and hospital outpatient departments more than tripled; those ordered or provided by emergency departments quadrupled.

▶ The rate of knee replacement surgery performed in patients aged 45 years and older rose 70% during the same interval, from 26 to 45 per 10,000 population. The rate of total hip replacement surgery increased by 33%, and that of partial hip replacements increased by 60%.

dose-related respiratory depression by acting directly on brain stem respiratory centers (see **OVERDOSAGE**). 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 depres-sion sion.

Skin and Subcutaneous Tissue Disorders Rash, pruritus

DRUG ABUSE AND DEPENDENCE

TussiCaps[®] extended-release capsules are Schedule III narcotics. Psychic dependence, physical dependence narcotics. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of narcotics; therefore, TussiCaps[®] extended-release capsules should be prescribed and administered with caution. However, psychic 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 adminis-tration 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. therapy.

OVERDOSAGE

OVERDOSAGE Signs and Symptoms – Serious overdosage with hydrocodne is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence pro-gressing 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 mani-festations of chlorpheniramine overdosage may vary from central nervous system depression to stimulation. Treatment – Primary, attention should be given to the

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 or controlled ventilation. The narcotic antagonist naloxone hydrochloride is a specific artidote for respiratory depres-sion which may result from overdosage or unusual sensi-tivity to narcotics including hydrocodone. Therefore, an appropriate dose of naloxone hydrochloride should be administered, preferably by the intravenous route, simulta-neously 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 pre-scribing information for naloxone hydrochloride. An antag-onist should not be administered in the absence of clinical scribing information for naioxone hydrochionde. An antag-onist should not be administered in the absence of clinical-ly 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.

A Schedule CIII Narcotic.

For Medical Information Contact: Product Monitoring Department Phone: 800-778-7898

Manufactured by: Mallinckrodt Inc Hazelwood, Missouri 63042 U.S.A.

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► The rate of angioplasty without stent placement declined by 80% during the past decade. Drug-eluting stents have rapidly replaced bare-metal stents and were used in 75% of angioplasties in 2006.

► The number of assisted reproductive technology cycles doubled during the past decade, with the fastest rate of growth occurring in women older than 40 (11% per year).

▶ The rate of outpatient upper endoscopies rose by 90%, and the rate of outpatient colonoscopy tripled during the same interval.

► The use of diabetes drugs among patients aged 45 and older increased approximately 50%, and that of statins soared 10-fold in the past decade.

▶ The percentage of people taking at least one prescription drug during the preceding month rose from 38% in the 1980s and 1990s to 47% in recent years. The percentage taking three or more prescription drugs increased from 11% to 21% during that time.

The report also detailed trends in mortality. Both life expectancy and infant mortality have been improving but continue to lag behind levels found in most developed countries. Infant mortality in the United States is now 27% lower than it was in 1990.

American men now can expect to live 3.5 years longer, and women can expect to live 1.6 years longer, than they did in 1990. Overall U.S. life expectancy was 77.9 years in 2007, a record high.

Life expectancy increased more among blacks than among whites, but a gap between the races persists. In 1990, life expectancy for whites was 7 years longer than that for blacks; by 2007, that gap narrowed to 4.6 years.

Mortality from heart disease, stroke, and cancer continues to decline, while mortality from chronic respiratory diseases and unintentional injuries has remained stable. The leading cause of death for people aged 1-44 years is unintentional injuries; for people aged 45-64 years, cancer; and for people aged 65 and older, heart disease.

With regard to chronic physical, mental, or emotional conditions, the report noted that the proportion of workingage adults who reported that a chronic condition limited their activity has remained steady at approximately 10%. Arthritis and other musculoskeletal disorders were the most frequent causes of such limitations in adults.

Mental illness was the second-leading cause of limitation due to chronic conditions in adults aged 18-44 years; heart and circulatory disorders were the second-leading cause in older adults, but mental illness was frequently cited in this age group as well.

In adolescents, mental, emotional, or behavioral problems were frequently cited as chronic conditions that limited activity.

The full report is available at www.cdc. gov/nchs/hus.htm.