

IOM Report Identifies National Vaccine Priorities

BY MIRIAM E. TUCKER

The National Vaccine Plan should prioritize limited resources to meet unmet health needs and to increase funds for safety research and communication, the Institute of Medicine said in a new report.

The Institute of Medicine, an independent advisory body, launched its new report “Priorities for the National Vaccine

Plan” at a press briefing in December.

The National Vaccine Plan, first released in 1994, was mandated by the National Childhood Vaccine Injury Act of 1986. A draft update was issued in 2008. Given current budgetary constraints, the National Vaccine Program Office, part of the Department of Health and Human Services, requested guidance from the IOM on prioritization of activities. The plan is expected to be finalized this year.

Dr. Claire Broome, who chaired the 18-member multidisciplinary committee that wrote the report, said the new plan will be broader in scope than was the 1994 document. That one was intended to be used primarily by the NVPO, which coordinates all vaccine-related activities of multiple federal agencies. In contrast, the new plan will also be aimed at other public and private vaccine stakeholders, including public health

offices, health care providers, pharmaceutical companies, health care organizations, and the general public.

“Changes in society, medicine, science, and communication were important considerations for our committee as we looked at the plan for the future of vaccines and immunization,” said Dr. Broome of the Rollins School of Public Health, Emory University, Atlanta.

The document identifies 18 “priority actions” distributed among five main goals, as well as two additional recommendations regarding the role of the plan as the primary tool to be used for all agencies with roles in the NVPO, and for allocation of resources to ensure implementation of vaccine-related activities within the plan.

Under the heading of Vaccine Development, the report advises that the plan incorporate improvements in the vaccine regulatory process that reflect current science and “encourage innovation without compromising safety and efficacy.” Evidence-based approaches should be used to prioritize new and improved vaccine candidates and to develop specifications for high-priority vaccines. Acceleration of high-priority vaccine development should involve the National Institutes of Health and the Department of Defense, as well as private sector partners.

With regard to Vaccine Safety, the committee said that the plan should establish a process to identify potential vaccine safety hypotheses for future basic, clinical, or epidemiologic research through review of data from existing surveillance systems. A framework should be developed to prioritize the national vaccine safety research agenda, and the plan should establish a permanent vaccine safety subcommittee within the National Vaccine Advisory Committee.

The IOM report includes recommendations for development of a national communication strategy on vaccines and immunization targeting both the public and health care professionals. There should be a process for identifying research needs to inform the national communication strategy, the report advises.

Recommendations regarding Vaccine Use and Supply include the development of strategies to eliminate financial barriers to immunization, the application of research and best practices to improve patient access, the exploration of nontraditional approaches to surveillance of disease, vaccine safety, and vaccine coverage.

Global Vaccine Issues within the new National Vaccine Plan should include engagement of U.S. federal agencies and partners in building immunization capacity in low- to middle-income countries through the provision of both expertise and financial resources, and also the endorsement of global policy frameworks to further global adherence to differential pricing in order to ensure access to needed vaccines in all countries.

Dr. Broome and the rest of the committee members do not have any conflicts of interest, according to an IOM spokeswoman. ■

BRIEF SUMMARY - Consult full prescribing information before use.

TussiiCaps®
(Hydrocodone Polistirex and Chlorpheniramine Polistirex)
Extended-Release Capsules



Rx only

CONTRAINDICATIONS

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

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

WARNINGS

Respiratory Depression – As with all narcotics, TussiiCaps® 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 TussiiCaps® extended-release capsules are 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 TussiiCaps® extended-release capsules are 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 TussiiCaps® extended-release capsules to pediatric patients 6 years of age and older. Overdose or concomitant administration of TussiiCaps® extended-release capsules 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, TussiiCaps® 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

As with all narcotics, TussiiCaps® extended-release capsules 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. TussiiCaps® 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 TussiiCaps® extended-release capsules are 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 TussiiCaps® extended-release capsules may exhibit an additive CNS depression. 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 TussiiCaps® 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 adequate and well-controlled studies in pregnant women. TussiiCaps® 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 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 TussiiCaps® 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 for serious adverse reactions in nursing infants from TussiiCaps® 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 TussiiCaps® extended-release capsules are contraindicated in children less than 6 years of age (see **CONTRAINDICATIONS and ADVERSE REACTIONS, Respiratory, Thoracic and Mediastinal Disorders**).

TussiiCaps® 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 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 TussiiCaps® extended-release capsules 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**).

TussiiCaps® extended-release capsules may produce

dose-related respiratory depression by acting directly on brain stem respiratory centers (see **OVERDOSAGE**). Use of TussiiCaps® in children less than 6 years of age has been associated with fatal respiratory depression. Overdose with TussiiCaps® 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

TussiiCaps® extended-release capsules are Schedule III narcotics. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of narcotics; therefore, TussiiCaps® extended-release capsules should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when TussiiCaps® 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, 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 by 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.

A Schedule CIII Narcotic.

For Medical Information

Contact: Product Monitoring Department
Phone: 800-778-7898

Manufactured by:
Mallinckrodt Inc.
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