

The Endocrine Society's Recommended Criteria for Metabolic Risk

Clinical measure	Any three of these five elements
Waist circumference	≥ 102 cm for men or ≥ 88 cm for women (non-Asian); ≥ 90 cm for East Asian and South Asian men or ≥ 80 cm for East Asian or South Asian women
Fasting triglycerides	150 mg/dL or higher, or patients taking medication for high triglycerides
HDL cholesterol	HDL < 40 mg/dL in men or < 50 mg/dL in women, or patients taking medication for low HDL
Blood pressure	130 mm Hg systolic or higher; or 85 mm Hg diastolic or higher, or patients taking medication for hypertension
Fasting glucose	100 mg/dL or higher, or patients taking medication for elevated glucose

Note: The Endocrine Society recommends the American Heart Association/National Heart, Lung, and Blood Institute's criteria for metabolic syndrome as a screening tool to reduce risk for cardiovascular disease and type 2 diabetes.

Sources: The Endocrine Society, AHA/NHLBI

Strategy Eyes Heart Disease And Diabetes

BY HEIDI SPLETE
Senior Writer

A new clinical practice guideline from the Endocrine Society provides strategies for keeping type 2 diabetes and cardiovascular disease at bay in adults with metabolic syndrome.

"This guideline focuses on [those] with the components of the metabolic syndrome who do not yet have diagnosed cardiovascular disease or type 2 diabetes mellitus, and on the steps that can be taken to prevent these two diseases," the guideline authors said in an introductory statement.

Health care providers are urged to make metabolic risk reduction part of their regular practice by measuring waist circumference, blood pressure, fasting lipid profiles, and fasting glucose as part of every routine clinical visit. (See table.)

If patients approach or fall into the at-risk category for any of these measures, they should be counseled on how to reduce their disease risk with lifestyle management, including a healthy diet, adequate exercise, and weight loss if needed.

The guideline appeared in print in the *Journal of Clinical Endocrinology and Metabolism* and is now available online at www.endojournals.org.

It defines metabolic risk as the risk for CVD and type 2 diabetes based on several elements, including elevated triglycerides, reduced HDL cholesterol, increased plasma glucose levels, hypertension, enlarged waist circumference, a prothrombotic state, and a proinflammatory state.

It also recommends a global risk assessment for signs on cardiovascular and coronary heart disease every 10 years for patients meeting the criteria for metabolic risk. The LDL cholesterol measure should be used to target lipoprotein-lowering therapy if lifestyle modification has been insufficient.

Patients meeting criteria for prediabetes based on measurements from a routine visit should be screened for diabetes at 1- to 2-year intervals using a fasting plasma glucose test or a 2-hour oral glucose tolerance test.

The society suggests that physicians screen for metabolic risk factors using the American Heart Association/National Heart, Lung, and Blood Institute definition at each clinical visit. "The finding of three or more components especially should alert the clinician to a patient at metabolic risk," the guideline states.

The guideline should not be considered inclusive or exclusive of other approaches to care, the authors noted.

Dr. James L. Rosenzweig of Boston University, chair of the task force that developed the guidelines, stated that he had no financial conflicts to disclose. Other members of the task force had no financial interests to disclose, but they have served on speakers bureaus for multiple pharmaceutical companies including Novartis, Pfizer Inc., Merck & Co., and GlaxoSmithKline. ■

ELSEVIER GLOBAL MEDICAL NEWS

BRIEF SUMMARY - Consult full prescribing information before use.

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

Rx only

CONTRAINDICATIONS

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

The use of TussisCaps® 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, TussisCaps® 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 TussisCaps® 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 TussisCaps® 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 TussisCaps® extended-release capsules to pediatric patients 6 years of age and older. Overdose or concomitant administration of TussisCaps® 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, TussisCaps® 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, TussisCaps® 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. TussisCaps® 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 TussisCaps® 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 TussisCaps® 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 TussisCaps® 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. TussisCaps® 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 TussisCaps® 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 TussisCaps® 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 TussisCaps® extended-release capsules are contraindicated in children less than 6 years of age (see **CONTRAINDICATIONS and ADVERSE REACTIONS, Respiratory, Thoracic and Mediastinal Disorders**).

TussisCaps® 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 TussisCaps® 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**). TussisCaps® extended-release capsules may produce

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

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

A Schedule CIII Narcotic.

For Medical Information

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

Manufactured by:
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Hazelwood, Missouri
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