

practical import is that, if another intervention allows pain to be relieved and therefore morphine to be discontinued, it is important to reduce the dose in a step-wise fashion, analogous to that employed for corticosteroid withdrawal to avoid problems with withdrawal syndrome. Even if withdrawal syndrome occurs from oral opiates, it is generally mild and not of the type seen in the addict population.

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ACUTE SINUSITIS: IMPACT AND MANAGEMENT

Sinusitis recently surpassed arthritis as the nation's most prevalent chronic disease: 31 million Americans are currently afflicted, according to the Center for Disease Statistics. While the vast majority of

sinusitis cases are self-limiting, the disease has a large impact on the nation's health care bill. Sinusitis was the reason for 16 million doctor visits in 1989, 90% of which were to primary care physicians. In fact, 33% to 50% of all visits to primary care physicians are for upper respiratory infections and their sequelae, and 0.5% to 5% of these are associated with sinusitis. Further, \$150 million is spent on cold remedies annually, and the amount seems to be growing. Antihistamine purchases, which account for \$100 million of the total, increased by 26% from 1988 to 1989.

Acute sinusitis, which can affect any of the sinuses (frontal, maxillary, ethmoidal, or sphenoidal), usually originates from an upper respiratory infection by *Streptococcus* or *Hemophilus* organisms. Therefore, the recommended management should include application of antibiotics, topical and systemic decongestants, and mucolytic agents. The antibiotic of choice is amoxicillin, given in doses of 500 mg three times daily for 14 to 21 days. Topical decongestants should be used for

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Brief Summary: Please see package insert for full prescribing information.

INDICATIONS AND USAGE: Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS: Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS: General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which augment systemic absorption include the applications of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area and under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See PRECAUTIONS—Pediatric Use.) If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient: Patients using topical corticosteroids should receive the following information and instructions. 1. The medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes. 2. Patients should be advised not to use this medication for any disorder other than for

which it was prescribed. 3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician. 4. Patients should report any signs of local adverse reactions especially under occlusive dressing. 5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests: The following tests may be helpful in evaluating the HPA axis suppression:
Urinary free cortisol test
ACTH stimulation test

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy Category C: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities NOT likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use: Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimula-

tion. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS: The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

OVERDOSAGE: Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (See PRECAUTIONS).

DOSE AND ADMINISTRATION: Topical corticosteroids are generally applied to the affected area as a thin film three or four times daily depending on the severity of the condition. Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED: 1 oz. tube

CAUTION: Federal law prohibits dispensing without prescription.

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References: 1. McEvoy GK, ed. *Drug Information '88*. Am J Hosp Pharm. 1988:2039-2040. 2. *Goodman and Gilman's The Pharmacological Basis of Therapeutics*. 7th ed. New York: Macmillan Publishing Co; 1985:312.

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periods of not more than 5 days due to possible rebound effects. Contrary to popular belief, antihistamines should be avoided as they tend to thicken secretions, thus increasing blockage and inhibiting drainage.

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OSTEOPOROSIS: WHEN TO USE CALCITONIN

Calcitonin is the treatment of choice for specific groups of osteoporotic patients. Because of its unique analgesic effect, calcitonin is recommended for patients who have significant pain that cannot be controlled by other methods. Calcitonin has also been shown to be beneficial in patients with steroid-induced osteoporosis. In studies monitoring patients during a 6-month period of steroid treatment, salmon calcitonin injections were found to prevent bone resorption.

Prior to beginning calcitonin treatment, tolerance testing should be conducted to eliminate the risk for allergic reactions. The typical management plan calls for the injection of 50 to 100 units daily or every other day. When used as an analgesic, the injections should be administered for a 2-week trial period, after which, if no improvement is apparent, treatment should be discontinued. If a favorable response is noted within 2 weeks, treatment should be continued for several more weeks, then reduced to three times per week and gradually discontinued over the next few months. At that point, the pain has often been effectively controlled; if not, it is sometimes necessary to resume the drug regimen. When used to treat osteoporosis, treatment should be conducted for at least 2 or 3 years. No trial period is necessary since the drug's efficacy for this purpose may not be readily apparent. Assessing bone mineral density is the best monitor of efficacy.

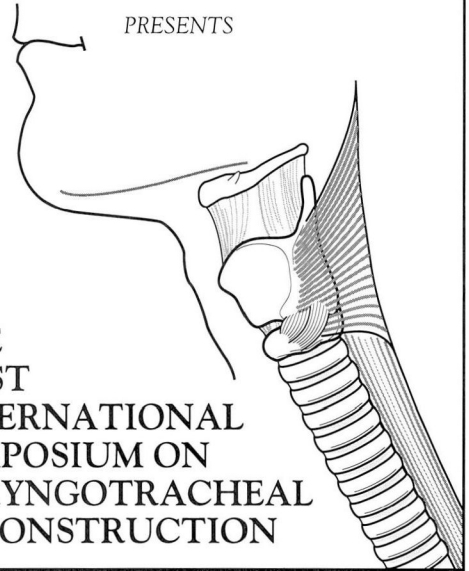
No significant toxicity associated with long-term use of calcitonin has been reported since the agent was first introduced 20 years ago. Unlike other analgesics, the drug does not induce central nervous system reactions. Nausea is the only commonly experienced side effect. Antiemetics counteract the effect. An intranasal form of calcitonin currently under investigation appears to produce an even lower incidence of side effects.

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**FOR FURTHER INFORMATION
REGARDING THIS SYMPOSIUM, CONTACT:**

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