

LORELCO*

PROBUCOL

ANTHYPERCHOLESTEROLEMIC AGENT

INDICATIONS: LORELCO is indicated as an adjunct to diet for the treatment of hypercholesterolemia associated with elevated low density lipoproteins, and may be useful in lowering elevated cholesterol levels in patients with mixed hyperlipidemia (hypercholesterolemia and hypertriglyceridemia), where the hypercholesterolemia is the moiety of most concern.

CONTRAINDICATIONS: LORELCO is contraindicated in patients known to be hypersensitive to the drug. The safety of LORELCO has not been established in pregnancy and therefore, it should not be used in these circumstances, neither should it be used in nursing mothers since animal studies have shown that the drug is excreted in milk.

WARNINGS: Strict birth control procedures must be exercised by women of child-bearing potential. In the event LORELCO is discontinued, such procedures should be followed for at least the subsequent six months. In the event a marked and sustained elevation in the serum triglyceride level occurs that is not related to diet, consideration should be given to discontinuing treatment with LORELCO. (See PRECAUTIONS).

PRECAUTIONS: Before instituting therapy with LORELCO (probulco) an attempt should be made to control serum cholesterol by appropriate dietary regimens, weight reduction, and the treatment of any underlying disorder which might be the cause of the hypercholesterolemia.

Because LORELCO is intended for long term administration, adequate baseline studies should be performed to determine that the patient has elevated serum cholesterol levels. Serum cholesterol levels should be determined frequently during the first few months of treatment and periodically thereafter. A favorable trend in cholesterol reduction should be evident during the first two months of LORELCO administration. This regimen should be followed as long as the trend continues and a decision should be made by the fourth month as to whether an adequate reduction is being maintained.

A baseline for serum triglycerides should also be established and serum triglyceride levels should be determined periodically. If a marked sustained rise in serum triglycerides is observed during probulco therapy, consideration should be given to improved diet compliance, alcohol abstinence, further calorie restriction or adjustment of carbohydrate intake. Probulco should not be continued if this hypertriglyceridemia persists.

Limited experience from clinical studies indicates that an increase in serum triglyceride levels can sometimes occur without necessarily an additive effect being apparent on the serum cholesterol, when LORELCO is used concomitantly with clofibrate. The combination of LORELCO and clofibrate is, therefore, not recommended.

The safety and effectiveness of LORELCO has not been established in children.

ADVERSE REACTIONS: The adverse reactions associated with LORELCO (probulco) are generally mild to moderate and of short duration.

The most commonly affected system is the gastrointestinal tract. Diarrhea occurs in about one in 10 patients. Other adverse gastrointestinal reactions in descending order of frequency are flatulence, abdominal pain, nausea and vomiting. These reactions are usually transient and seldom require the drug to be discontinued. During the clinical studies, LORELCO was discontinued in about 2% of the patients because of adverse gastrointestinal reactions.

Less frequent adverse reactions are: hyperhidrosis, fetid sweat and angioneurotic edema occurring in less than one in 500 subjects.

An idiosyncratic reaction characterized by dizziness, palpitations, syncope, nausea, vomiting and chest pain has been reported.

Other events, where the relationship to LORELCO has not been established include: headache, dizziness, paresthesia and eosinophilia, observed in about one in 50 subjects; consistently low hemoglobin and/or hematocrit values, observed in about one in 100 patients; rash, pruritus, impotency, insomnia, conjunctivitis, tearing, blurred vision, tinnitus, diminished sense of taste and smell, enlargement of a multinodular goiter, anorexia, heartburn, indigestion, vomiting, gastrointestinal bleeding, ecchymosis and petechiae, thrombocytopenia, nocturia, and peripheral neuritis, observed with a frequency of about one to six per thousand subjects.

Elevations of the serum transaminases (glutamic-oxalacetic and glutamic-pyruvic), bilirubin, alkaline phosphatase, creatine phosphokinase, uric acid, blood urea nitrogen and blood glucose above the normal range were observed on one or more occasions in various patients treated with LORELCO (probulco). Most often these were transient and/or could have been related to the patient's clinical state or other modes of therapy. Although the basis for the relationship between probulco and these abnormalities is not firm, the possibility that some of these are drug related cannot be excluded. In the controlled trials the incidence of abnormal laboratory values was not higher in the patients treated with probulco than in the patients who received placebo.

DOSAGE AND ADMINISTRATION: The recommended adult dose is 500 mg (two 250 mg tablets), twice daily, with morning and evening meals.

AVAILABILITY: LORELCO is a white, film-coated tablet, containing 250 mg probulco, available in bottles of 120 tablets.

Product monograph available upon request.



DOW PHARMACEUTICALS
Dow Chemical of Canada, Limited
380 Elgin Mills Road East,
Richmond Hill, Ontario



*Trademark of The Dow Chemical Company

ficers, alarmed at the grotesque appearance of an acute ailment in their trusty warriors, excused them from duty and often packed them off to hospital — much to the delight of the sufferers.

Soldiers far from hearth and home have repeatedly exploited the limitless possibilities for malingering. In these instances, by nicking the inside of the cheek with a razor blade, pinching the nose, shutting the mouth and expelling a few quick forced breaths, they created a new tropical disease.

IAN MIDDLEMASS, MD
Department of radiology
Royal Inland Hospital
Kamloops, BC

Reference

1. Box HK: *Oxygen Insufflation in Periodontal Diseases*, CC Thomas, Springfield, Ill, 1955, p 88

To the editor: The article by Clement and Lommel brings to mind two cases I have seen in which the cause of cervicofacial emphysema was other than dental surgery. In the Middle East during World War II a young serviceman was admitted to the psychiatric unit with cervicofacial emphysema. I would not have thought this remarkable, but shortly afterwards a second person from the same unit was admitted. As these servicemen were homosexual partners, one would have thought there was a connection, but where?

Eventually the truth came out. The emphysema was self-induced: the men used the pricker of a Primus stove to prick the buccal mucosa, held the nose, and then, with the mouth closed, blew hard. They hoped to get a medical discharge, but it was on grounds of homosexuality that they left the service.

MYRE SIM, MD, FRCP (EDIN), FRC PSYCH, FRCP[C], DPM
Professor of psychiatry
University of Ottawa
Ottawa, Ont.

The Heimlich maneuver

To the editor: The Heimlich maneuver, first publicized in 1974, has been reported to be very effective in expelling boluses by pressurizing the lungs to an average of 31 mm Hg.¹ However, as judged from the unabated mortality, competent assistance of this type is seldom available

to victims. The successive mortality rates for choking (suffocation from ingestion of food or an object) from 1971 through 1976 in the United States were 2877, 2830, 3013, 2991, 3106 and (estimated) 2900.²

I believe that research methods must be developed to determine the effectiveness of such unproven methods as back-slapping and the self-applied Heimlich maneuver in the hope that an effective and easy-to-remember technique will result. Opening the mouth widely and forcing the tongue out might be found to allow a sufficient opening so that a victim could continue to breathe or even expel an obstruction. Also to be considered is that, in normal males, maximum forced expiration produces an average pulmonary pressure of 114 mm Hg,³ a pressure more than three times that produced by the Heimlich maneuver. Because a million lives will be at stake over the next 20 years, this subject demands a more systematic approach than it has been given in the past.

JOHN SPRINGFIELD, MA
Cancer research laboratory
Veterans Administration Hospital
Minneapolis, Minnesota

References

1. HEIMLICH HJ: Food asphyxiation (C). *Can Med Assoc J* 112: 1383, 1975
2. National Safety Council: *Accident Facts*, Chicago, 1975-77
3. RAHN H, OTIS AB, CHADWICK LE, et al: The pressure volume diagram of the thorax and lung. *Am J Physiol* 146: 161, 1946

Cesarean section: what is an acceptable rate? (correction)

F. Toll, manager of the management information section of the Manitoba Health Services Commission, has brought the attention of the Journal and Dr. T.F. Baskett to some discrepancies in the data cited in his editorial (118: 1019, 1978). The second sentence of the second paragraph, with italics indicating the corrected figures, should read: "In Manitoba the overall rate had doubled since 1971, reaching 9.8% in 1976, and varied from 12.7% to 16.2% (average 14.2%) in teaching hospitals, 6.1% to 13.1% (average 9.6%) in community hospitals served by specialists in obstetrics and other fields, and 0% to 15.4% (average 5.5%) in rural hospitals . . ." — Ed.