

Clinton, Obama Pitch Patient Safety Legislation

BY MARY ELLEN SCHNEIDER
Senior Writer

Two Democratic senators are aiming to move patient safety to the center of the medical liability debate.

Sen. Hillary Rodham Clinton (D-N.Y.) and Sen. Barack Obama (D-Ill.) have introduced legislation that would provide grant funding for physicians, hospitals, and health systems to routinely report medical errors to a national database. In cases in which patients were harmed, the hospitals and physicians involved would disclose the error and

offer to enter into confidential negotiations on compensation. Any disclosures and apologies from physicians would be considered confidential under the bill.

"For too long, our health care system has discouraged the kind of communication needed to find and correct the conditions that lead to medical errors," Sen. Clinton said in a statement. "Our bill puts patient safety first and creates an avenue for doctors and patients to find solutions outside of the courtroom."

The two senators recently touted the benefits of the bill, the National Medical Error Disclosure and Compensation Act (S. 1784), in a perspective published in the

New England Journal of Medicine (2006;354:2205-8).

In addition, medical liability insurers who participate in the program would be required to put a portion of any savings realized toward reducing physician premiums. For health care providers who participate, a portion of the savings must be used for activities that result in reduced medical errors and improved patient safety.

Some physician leaders, however, are skeptical that the bill will gain any traction in an election year. The legislation was introduced last September and was referred to the Senate Committee on Health, Education, Labor, and Pensions. ■

NEW FOR ACNE

Introducing
NEW, Rx Only
BENZIQ™
(benzoyl peroxide)

A balance of effective clearing and soothing hydration

The unique hydrating complex makes the difference

- Hyaluronic acid**
Powerful humectant, carries 1000x its own weight in water^{1,2}
- Panthenol**
Promotes moisturization and hydration of the stratum corneum^{2,3}
- Glycerin**
Attracts and retains moisture, softens skin^{2,4}

Please see adjacent full Prescribing Information.

And for sensitive skin...
BENZIQ LS GEL 2.75%
(Low Strength)
50 g Tube

BENZIQ WASH 5.25%
175 g Tube

BENZIQ GEL 5.25%
50 g Tube

*BenzIQ Wash + GEL
D.A.W.*

BENZIQ™ GEL (benzoyl peroxide) 5.25%
BENZIQ™ WASH (benzoyl peroxide) 5.25%
BENZIQ™ LS GEL (benzoyl peroxide) 2.75%

DESCRIPTION

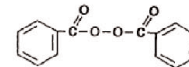
BenzIQ™ LS Gel (benzoyl peroxide 2.75%), **BenzIQ™ Gel** (benzoyl peroxide 5.25%), and **BenzIQ™ Wash** (benzoyl peroxide 5.25%) are products intended for topical administration which contain benzoyl peroxide for use in the treatment of acne vulgaris.

BenzIQ™ LS Gel Contains: Benzoyl Peroxide 2.75% in an aqueous vehicle containing Allantoin, Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Carbomer, Cetyl Alcohol, Citric Acid, Disodium EDTA, Disodium Oleamido MEA-Sulfosuccinate, Glycerin, Panthenol, Poloxamer, Purified Water, Sodium Hyaluronate, and Triethanolamine.

BenzIQ™ Gel Contains: Benzoyl Peroxide 5.25% in an aqueous vehicle containing Allantoin, Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Carbomer, Disodium EDTA, Disodium Oleamido MEA-Sulfosuccinate, Glycerin, Panthenol, Poloxamer, Purified Water, Sodium Hyaluronate, and Triethanolamine.

BenzIQ™ Wash Contains: Benzoyl Peroxide 5.25% in an aqueous vehicle containing Allantoin, Aloe Barbadensis Leaf Juice, Benzyl Alcohol, Carbomer, Cetyl Alcohol, Citric Acid, Disodium EDTA, Disodium Oleamido MEA-Sulfosuccinate, Glycerin, Glyceryl Stearate, Laureth-12, Magnesium Aluminum Silicate, Panthenol, PEG-100 Stearate, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Hyaluronate, Sodium Lauryl Sulfacetate, Sodium Octoxynol-2 Ethane Sulfonate, and Xanthan Gum.

The structural formula of benzoyl peroxide is:



Benzoyl peroxide has a molecular weight of 242.23.

CLINICAL PHARMACOLOGY

Mechanism of Action

The exact mechanism of action of benzoyl peroxide in acne vulgaris is not known. Benzoyl peroxide is an antibacterial agent with demonstrated activity against *Propionibacterium acnes*. This action combined with the mild kerolytic effect of benzoyl peroxide is believed to be responsible for its usefulness in acne.

Benzoyl peroxide is absorbed by the skin where it is metabolized to benzoic acid and excreted as benzoate in the urine.

INDICATIONS AND USAGE

BenzIQ™ LS Gel (benzoyl peroxide 2.75%), **BenzIQ™ Gel** (benzoyl peroxide 5.25%) and **BenzIQ™ Wash** (benzoyl peroxide 5.25%) are indicated for the topical treatment of acne vulgaris.

CONTRAINDICATION

Each of the topical products are contraindicated in patients with a history of hypersensitivity to any of the ingredients in each product.

PRECAUTIONS

General: For external use only. If severe irritation develops, discontinue use and institute appropriate therapy. After reaction clears, treatment may often be resumed with less frequent application. These preparations should not be used in or near the eyes or on mucous membranes.

Patient Information and Cautions: Avoid contact with eyes, eyelids, lips, and mucous membranes. If accidental contact occurs, rinse with water. Contact with any colored material (including hair and fabric) will result in bleaching or discoloration. If excessive irritation develops, discontinue use and consult your physician. When using this product, avoid unnecessary exposure to the sun and use a sunscreen.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Data from several studies employing a strain of mice that is highly susceptible to developing cancer suggest that benzoyl peroxide acts as a tumor promoter. The clinical significance of these findings to humans is unknown. Benzoyl peroxide has been found to be mutagenic (Ames Test) and there are no published data indicating it impairs fertility.

Pregnancy: Teratogenic Effects: Pregnancy Category C: Animal reproduction studies have not been conducted with benzoyl peroxide. It is not known whether benzoyl peroxide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzoyl peroxide should be used by a pregnant woman only if clearly needed. There are no available data on the effect of benzoyl peroxide on the later growth, development, and functional maturation of the unborn child.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when benzoyl peroxide is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children under 12 years of age have not been established.

ADVERSE REACTIONS

Allergic contact dermatitis and dryness have been reported with topical benzoyl peroxide therapy.

OVERDOSAGE

If excessive scaling, erythema, or edema occurs, the use of this preparation should be discontinued. To hasten resolution of the adverse effects, cool compresses may be used. After symptoms and signs subside, a reduced dosage schedule may be cautiously tried if the reaction is judged to be due to excessive use and not an allergic reaction.

DOSAGE AND ADMINISTRATION

BenzIQ™ LS Gel and **BenzIQ™ Gel** can be applied once or twice daily to the affected areas or as directed by your physician. Use after washing with water and a mild cleanser such as **BenzIQ™ Wash**.

BenzIQ™ Wash should be shaken well before use. The affected areas should be washed once or twice daily or as directed by your physician. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, massage gently into skin for 10 to 20 seconds, working into a full lather. Rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing cleanser off sooner or using the cleanser less often.

HOW SUPPLIED

BenzIQ™ LS Gel (benzoyl peroxide 2.75%) is supplied in 50 g tubes, NDC 13453-225-50

BenzIQ™ Gel (benzoyl peroxide 5.25%) is supplied in 50 g tubes, NDC 13453-240-50

BenzIQ™ Wash (benzoyl peroxide 5.25%) is supplied in 175 g tubes, NDC 13453-200-18

Store at 15°-25°C (59°-77°F). Protect from freezing.

Rx Only

Manufactured for: Chester Valley Pharmaceuticals Inc., Malvern, PA 19355
Manufactured by: Harmony Labs, Inc., Landis, NC 28088

BZ101 1105

www.benziq.com

References: 1. Data on file. Chester Valley Pharmaceuticals, Inc., Malvern, PA. 2. BenzIQ™ (benzoyl peroxide) prescribing information. 3. Ebner F, Heller A, Rippeke F, Tausch I. Topical use of dexpantenol in skin disorders. *Am J Clin Dermatol.* 2002;3:427-433. 4. Food and Drug Administration. Skin protectant drug products for over-the-counter human use; Final monograph. Final rule. *Federal Register.* 2003;68:33362-33381.

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