

## Brevoxyl<sup>®</sup> creamy wash

Combined Full Prescribing Information

**Brevoxyl-4 Creamy Wash** (benzoyl peroxide 4%)  
**Brevoxyl-8 Creamy Wash** (benzoyl peroxide 8%)

### Rx only

**DESCRIPTION:** Brevoxyl-4 and Brevoxyl-8 Gels are topical preparations containing benzoyl peroxide 4% and 8%, respectively, as the active ingredient in a gel vehicle containing purified water, cetyl alcohol, dimethyl isosorbide, fragrance, stethocaine, stearyl alcohol, and ceteareth-20.

Brevoxyl-4 and Brevoxyl-8 Cleansing Lotions are topical preparations containing benzoyl peroxide as the active ingredient. Brevoxyl-4 and Brevoxyl-8 Cleansing Lotions contain benzoyl peroxide 4% and 8%, respectively, in a lathering vehicle containing purified water, cetyl alcohol, citric acid, dimethyl isosorbide, octadecyl sodium, hydroxypropyl methylcellulose, lauridin-12 magnesium aluminum silicate, propylene glycol, sodium hydroxide, sodium lauryl sulfosuccinate, and sodium octoxy-2 ethane sulfonate.

Brevoxyl-4 and Brevoxyl-8 Creamy Washes are topical preparations containing benzoyl peroxide as the active ingredient. Brevoxyl-4 and Brevoxyl-8 Creamy Washes contain 4% and 8% benzoyl peroxide, respectively, in a lathering cream vehicle containing cetylalcohol, cocamidopropyl betaine, corn starch, dimethyl isosorbide, glycerin, glycolic acid, hydrogenated castor oil, imidurea, methylparaben, mineral oil, PEG-14M, purified water, sodium hydroxide, sodium PCA, sodium potassium lauryl sulfate, titanium dioxide.

The structural formula of benzoyl peroxide is:



**CLINICAL PHARMACOLOGY:** The exact method 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 keratolytic 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:** Brevoxyl Gel, Brevoxyl Cleansing Lotion, and Brevoxyl Creamy Wash are indicated for use in the topical treatment of mild to moderate acne vulgaris. Brevoxyl Gel, Brevoxyl Cleansing Lotion, and Brevoxyl Creamy Wash may be used as adjuncts in acne treatment regimens including antibiotics, retinoid acid products, and sulfur/salicylic acid containing preparations.

**CONTRAINDICATIONS:** Brevoxyl Gel, Brevoxyl Cleansing Lotion, and Brevoxyl Creamy Wash should not be used in patients who have shown hypersensitivity to benzoyl peroxide or to any of the other ingredients in the products.

**PRECAUTIONS: General** — For external use only. Avoid contact with eyes and mucous membranes. **AVOID CONTACT WITH HAIR, FABRICS OR CARPETING AS BENZOYL PEROXIDE WILL CAUSE BLEACHING.**

**Carcinogenesis, Mutagenesis, Impairment of Fertility** — Based upon all available evidence, benzoyl peroxide is not considered to be a carcinogen. However, data from a study using mice with the mild keratolytic effect of benzoyl peroxide acts as a tumor promoter. The clinical significance of the findings is not known.

**Pregnancy Category C** — Animal reproduction studies have not been conducted with benzoyl peroxide. It is also 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.

**Nursing Mothers** — It is not known whether this drug is excreted in human milk. Because 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 below the age of 12 have not been established.

**ADVERSE REACTIONS:** Contact sensitization reactions are associated with the use of topical benzoyl peroxide products and may be expected to occur in 10 to 25 of 1000 patients. The most frequent adverse reactions associated with benzoyl peroxide use are excessive erythema and peeling which may be expected to occur in 5 of 100 patients. Excessive erythema and peeling most frequently appear during the initial phase of drug use and may normally be controlled by reducing frequency of use.

**DOSE AND ADMINISTRATION:** Brevoxyl-4 and Brevoxyl-8 Gels — Therapy may be initiated with either Brevoxyl-4 Gel or Brevoxyl-8 Gel. The medication should be applied once or twice daily to the affected areas. Frequency of use should be adjusted to obtain the desired clinical response. Gentle cleansing of the affected areas prior to application of Brevoxyl-4 Gel or Brevoxyl-8 Gel may be beneficial. Clinically visible improvement will normally occur by the third week of therapy. Maximum lesion reduction may be expected after approximately eight to twelve weeks of drug use. Continuing use of the drug is normally required to maintain a satisfactory clinical response.

Brevoxyl-4 and Brevoxyl-8 Cleansing Lotions — Shake well before using. Wash the affected areas once a day during the first week, and twice a day thereafter as tolerated. Wet skin areas to be treated; apply Brevoxyl-4 or Brevoxyl-8 Cleansing Lotion, work to a full lather, rinse thoroughly and pat dry. Frequency of use should be adjusted to obtain the desired clinical response. Clinically visible improvement will normally occur by the third week of therapy. Maximum lesion reduction may be expected after approximately eight to twelve weeks of drug use. Continuing use of the drug is normally required to maintain a satisfactory clinical response.

Brevoxyl-4 and Brevoxyl-8 Creamy Washes — Shake well before using. Wash the affected areas once a day during the first week, and twice a day thereafter as tolerated. Wet skin areas to be treated; apply Brevoxyl-4 or Brevoxyl-8 Creamy Wash, work to a full lather, rinse thoroughly and pat dry. Frequency of use should be adjusted to obtain the desired clinical response. Clinically visible improvement will normally occur by the third week of therapy. Maximum lesion reduction may be expected after approximately eight to twelve weeks of drug use. Continuing use of the drug is normally required to maintain a satisfactory clinical response.

**HOW SUPPLIED:** Brevoxyl-4 Gel and Brevoxyl-8 Gel are supplied in 42.5g (1.5oz) and 90g (3.1oz) tubes. Brevoxyl-4 Gel 42.5g tube (NDC 0145-2374-06) 42.5g tube (NDC 0145-2384-06) 90g tube (NDC 0145-2374-08) 90g tube (NDC 0145-2384-08)

Brevoxyl-4 Cleansing Lotion and Brevoxyl-8 Cleansing Lotion are supplied in 237 g (10.5 oz) plastic bottles. Brevoxyl-4 Cleansing Lotion (NDC 0145-2310-05) Brevoxyl-8 Cleansing Lotion (NDC 0145-2410-05)

Brevoxyl-4 Creamy Wash and Brevoxyl-8 Creamy Wash are supplied in 170.1 g (6.0 oz) tubes. Brevoxyl-4 Creamy Wash (NDC 0145-2474-06) Brevoxyl-8 Creamy Wash (NDC 0145-2484-06)

Store at controlled room temperature, 15-30°C (59-86°F).

U.S. Patent Nos. 4,923,900, 6,433,024

Rev. 06/03



Santitas Laboratories, Inc.  
Carrollton, TX 75006

# Botox Can Soften Defects in Lower Face

BY NORRA MACREADY  
Los Angeles Bureau

NEWPORT BEACH, CALIF. — Perioral injections of Botox may be a remedy when patients have lines radiating from the lips, a hollow appearance around the mouth, or an elongated upper lip often associated with aging, Joel Cohen, M.D., said at the annual meeting of the Pacific Dermatologic Association.

Injecting a total of 6-10 U of botulinum toxin type A into the orbicularis oris muscle can soften the lines and give the patient a more animated expression. The treatment also augments the upper lip in some patients, giving them a fuller lip without having to use fillers, said Dr. Cohen, a clinical assistant professor of dermatology at the University of Colorado, Denver.

Identify the injection sites by having the patient purse her lips. Inject the Botox superficially, into the peaks of the musculature. Treat the lower lip as well as the

upper lip, "or it will look funny, and may accentuate any hyperfunctional musculature of the lower lip," he said.

Proper placement of the injections is important. Go too lateral, and you may weaken the lip elevators, which could result in a drooping lip and a risk of drooling. Injecting too medially or right at the midline could flatten the Cupid's bow.

Even under the best of circumstances, Botox treatments around the mouth may impair the patient's ability to purse her lips, whistle, drink from a straw, or pronounce the letters P and B. For those reasons, Dr. Cohen does not recommend this procedure to actors, singers, broadcast journalists, woodwind musicians, or scuba divers.

Moving farther down the face, Dr. Cohen said he has achieved good results injecting Botox into people with a dimpled, "golf-ball chin" that becomes especially prominent when they talk or chew. Feel along the chin for the bony margin, and

inject 3-5 U into the belly of the mentalis muscle. With use of such small quantities, the treatment can be considered a "lunchtime" procedure.

Dr. Cohen offered a few pearls for maximizing cosmetic results and patient comfort during a lower-face procedure:

► Everyone has some naturally occurring lip asymmetry. Document this in photographs before the procedure, in case there's any question about it later. Some patients may benefit from a touch-up procedure a few weeks after the initial one.

► Makeup can obscure facial landmarks or small potential pitfalls such as vascular structures. Have the patient wipe it off before you administer the injections.

► Diluting the Botox makes the injections easier to perform, with no difference in cosmetic results as long as you're using an appropriate total dose. Dr. Cohen uses preserved saline, which decreases the pain.

► A 31-gauge syringe with a short hub also makes the procedure less painful. ■

## Botox for Hyperhidrosis May Deserve Nerve Blockage

BY ROBERT FINN  
San Francisco Bureau

SANTA FE, N.M. — Botox is an effective treatment for hyperhidrosis, but the large number of units required is painful unless the clinician uses nerve blocks, George J. Hruza, M.D., said at a conference sponsored by the Skin Disease Education Foundation. However, topical anesthesia is sufficient for the axilla, said Dr. Hruza of the Laser and Dermatologic Surgery Center in Town and Country, Mo.

Treating palmar surfaces with Botox (botulinum toxin type A) requires blocks of the median and ulnar nerves. A radial nerve block is unnecessary, since that nerve innervates the dorsal surface of the hand.

The median nerve is right under the palmaris longus tendon and is best reached in the carpal tunnel. Have the patient touch his or her thumb and little fingers; the nerve will be found at the most proximal crease. One can approach from either side, angling the needle to go under the tendon. If an approach from one side proves unsuccessful, try from the opposite side.

"You can feel it pop in when you get to the carpal tunnel," Dr. Hruza said. "Then inject your anesthetic right in there. There's no big vein or artery there to worry about."

While the ulnar nerve can be reached in the wrist, he prefers to block this nerve by injecting at the elbow between the medial epicondyle and the olecranon process. It's important to avoid injections directly into the nerve, so if the patient shows any sign of paresthesia when the needle goes in, one should back away a bit before injecting. Dr. Hruza recalled one patient who suffered

from paresthesia for 4 months as a result of an anesthetic injection into the ulnar nerve.

Treating plantar surfaces requires blocks of the posterior tibial, sural, and superficial peroneal nerves, and, optionally, the deep peroneal nerve.

The posterior tibial nerve is next to the tibial artery, which is easy to find if you can feel the pulse. If you can't feel the pulse, you may want to use Doppler ultrasound to localize the artery. Dr. Hruza has one patient whose tibial artery and nerve are 2 cm out of place.

For the first few treatments, Dr. Hruza used Doppler ultrasound; after that, he was able to locate the artery without assistance.

After localizing the artery, insert the needle posterior to anterior, anteromedial to the bone, retract a few millimeters, and inject several milliliters of anesthetic.

The sural nerve is at about the same location on the other side of the ankle. However, there's no artery to guide the injection, which should be placed between the lateral malleolus and the Achilles tendon.

Anesthetize the superficial peroneal nerve by laying down a row of anesthetic in the subcutaneous plane on the front of the foot, extending from the medial to the lateral malleolus.

One may also choose to anesthetize the deep peroneal nerve with a deep injection lateral to the extensor hallucis longus tendon. Dr. Hruza chooses not to block this nerve, because it only innervates the web space between the first and second toes, and only one or two botulinum toxin injections will be made in that location.

The SDEF and this newspaper are wholly owned subsidiaries of Elsevier. ■

## Foam Pads May Spare Surgery

NEWPORT BEACH, CALIF. — A foam-rubber pad with a hole in it helps many patients avoid surgery for chondrodermatitis nodularis chronica helioides, P. Haines Ely, M.D., said at the annual meeting of the Pacific Dermatologic Association.

Chondrodermatitis nodularis chronica helioides (CNCH) is a painful pressure sore on the ear that occurs on actinically damaged skin. It is usually seen in middle-aged men, although rare cases have been reported in children who were paralyzed and always slept on the same side.

Traditionally, CNCH is removed by making a small slit in the skin with a scalpel and using curved scissors or a scalpel to snip out the damaged cartilage. The wound is then closed with sutures or with a drop of cyanoacrylate glue.

This approach is associated with a cure rate of about 80%, but there is also a recurrence rate of 10%-30%, said Dr. Ely, a dermatologist in private practice in Grass Valley, Calif.

He has had longer-term results with 1-inch-thick foam pads that he buys at a local surplus store in 8-foot sheets for about \$10 a sheet. He cuts the sheets into smaller pieces approximately the size of a standard pillow, and then cuts a hole where the patient's ear will go. He instructs the patient to slip the foam between the pillowcase and the pillow, and to sleep with the ear resting in the depression formed by the hole.

If the CNCH does not resolve within 1 month, Dr. Ely has the patient come in for surgical excision. So far, virtually none of his patients have returned for surgery.

"I've actually ruined my surgical practice for chondrodermatitis because this almost always works," Dr. Ely said.

—Norra MacReady

