

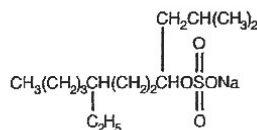
SOTRADECOL (Sodium tetradecyl sulfate)

FOR INTRAVENOUS USE ONLY

Rx Only

DESCRIPTION

Sodium tetradecyl sulfate is an anionic surfactant which occurs as a white, waxy solid. The structural formula is as follows:



$\text{C}_{19}\text{H}_{39}\text{NaO}_4$ 7-Ethyl-2-methyl-4-hendecanol sulfate sodium salt MW 316.44

Sotradecol® (sodium tetradecyl sulfate injection) is a sterile nonpyrogenic solution for intravenous use as a sclerosing agent.

1% (10 mg/mL): Each mL contains sodium tetradecyl sulfate 10 mg, benzyl alcohol 0.02 mL and dibasic sodium phosphate, anhydrous 4.0 mg in Water for Injection, pH 7.9; monobasic sodium phosphate and/or sodium hydroxide added, if needed, for pH adjustment.

3% (30 mg/mL): Each mL contains sodium tetradecyl sulfate 30 mg, benzyl alcohol 0.02 mL and dibasic sodium phosphate, anhydrous 9.0 mg in Water for Injection, pH 7.9; monobasic sodium phosphate and/or sodium hydroxide added, if needed, for pH adjustment.

CLINICAL PHARMACOLOGY

Sotradecol® (sodium tetradecyl sulfate injection) is a sclerosing agent. Intravenous injection causes intima inflammation and thrombus formation. This usually occludes the injected vein. Subsequent formation of fibrous tissue results in partial or complete vein obliteration that may or may not be permanent.

INDICATIONS AND USAGE

Sotradecol® (sodium tetradecyl sulfate injection) is indicated in the treatment of small uncomplicated varicose veins of the lower extremities that show simple dilation with competent valves. The benefit-to-risk ratio should be considered in selected patients who are great surgical risks.

CONTRAINDICATIONS

Sotradecol® (sodium tetradecyl sulfate injection) is contraindicated in previous hypersensitivity reactions to the drug; in acute superficial thrombophlebitis; valvular or deep vein incompetence; huge superficial veins with wide open communications to deeper veins; phlebitis migrans; acute cellulitis; allergic conditions; acute infections; varicosities caused by abdominal and pelvic tumors unless the tumor has been removed; bedridden patients; such uncontrolled systemic diseases as diabetes, toxic hyperthyroidism, tuberculosis, asthma, neoplasm, sepsis, blood dyscrasias and acute respiratory or skin diseases.

WARNINGS

Sotradecol® (sodium tetradecyl sulfate injection), should only be administered by a physician familiar with venous anatomy and the diagnosis and treatment of conditions affecting the venous system and familiar with proper injection technique. Severe adverse local effects, including tissue necrosis, may occur following extravasation; therefore, extreme care in intravenous needle placement and using the minimal effective volume at each injection site are important.

Emergency resuscitation equipment should be immediately available. Allergic reactions, including fatal anaphylaxis, have been reported. As a precaution against anaphylactic shock, it is recommended that 0.5 mL of Sotradecol® be injected into a varicosity, followed by observation of the patient for several hours before administration of a second or larger dose. The possibility of an anaphylactic reaction should be kept in mind, and the physician should be prepared to treat it appropriately.

Because of the danger of thrombosis extension into the

deep venous system, thorough preinjection evaluation for valvular competency should be carried out and slow injections with a small amount (not over 2 mL) of the preparation should be injected into the varicosity. Deep venous patency must be determined by angiography or noninvasive testing such as duplex ultrasound. Venous sclerotherapy should not be undertaken if tests such as Trendelenberg and Perthes, and angiography show significant valvular or deep venous incompetence.

The development of deep vein thrombosis and pulmonary embolism have been reported following sclerotherapy treatment of superficial varicosities. Patients should have post-treatment follow-up of sufficient duration to assess for the development of deep vein thrombosis. Embolism may occur as long as four weeks after injection of sodium tetradecyl sulfate. Adequate post-treatment compression may decrease the incidence of deep vein thrombosis.

PRECAUTIONS

GENERAL

Extreme caution must be exercised in the presence of underlying arterial disease such as marked peripheral arteriosclerosis or thromboangiitis obliterans (Buerger's Disease).

DRUG INTERACTIONS

No well-controlled studies have been performed on patients taking antiovarulatory agents. The physician must use judgment and evaluate any patient taking antiovarulatory drugs prior to initiating treatment with Sotradecol®. (See ADVERSE REACTIONS).

Heparin should not be included in the same syringe as Sotradecol®, since the two are incompatible.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

When tested in the L5178YTK +/- mouse lymphoma assay, sodium tetradecyl sulfate did not induce a dose-related increase in the frequency of thymidine kinase-deficient mutants and, therefore, was judged to be nonmutagenic in this system. However, no long-term animal carcinogenicity studies with sodium tetradecyl sulfate have been performed.

PREGNANCY

Teratogenic Effects – Pregnancy Category C. Animal reproduction studies have not been conducted with Sotradecol®. It is also not known whether Sotradecol® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sotradecol® should be given to a pregnant woman only if clearly needed and the benefits outweigh the risks.

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 Sotradecol® is administered to a nursing woman.

PEDIATRIC USE

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Local reactions consisting of pain, urticaria or ulceration may occur at the site of injection. A permanent discoloration may remain along the path of the sclerosed vein segment. Sloughing and necrosis of tissue may occur following extravasation of the drug. (See WARNINGS section).

Allergic reactions such as hives, asthma, hayfever and anaphylactic shock have been reported. Mild systemic reactions that

have been reported include headache, nausea and vomiting. (See WARNINGS section).

At least six deaths have been reported with the use of Sotradecol®. Four cases of anaphylactic shock leading to death have been reported in patients who received Sotradecol®. One of these four patients reported a history of asthma, a contraindication to the administration of Sotradecol®. See WARNINGS section).

One death has been reported in a patient who received Sotradecol® and who had been receiving an antiovarulatory agent. Another death (fatal pulmonary embolism) has been reported in a 36-year-old female treated with sodium tetradecyl acetate and who was not taking oral contraceptives.

DOSAGE AND ADMINISTRATION

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use if precipitated or discolored.

Sotradecol® (sodium tetradecyl sulfate injection) is for intravenous use only. The strength of solution required depends on the size and degree of varicosity. In general, the 1% solution will be found most useful with the 3% solution preferred for larger varicosities. **The dosage should be kept small, using 0.5 to 2 mL (preferably 1 mL maximum) for each injection, and the maximum single treatment should not exceed 10 mL.**

HOW SUPPLIED

Sotradecol® (sodium tetradecyl sulfate injection)

1% (10 mg/mL) - 2 mL vials; in packages of 5 (NDC 67457-162-02)
3% (30 mg/mL) - 2 mL vials; in packages of 5 (NDC 67457-163-02)

STORAGE

Store at 20°C to 25°C (68°F to 77°F) (See USP Controlled Room Temperature).

ANIMAL TOXICOLOGY

The intravenous LD₅₀ of sodium tetradecyl sulfate in mice was reported to be 90 ± 5 mg/kg.

In the rat, the acute intravenous LD₅₀ of sodium tetradecyl sulfate was estimated to be between 72 mg/kg and 108 mg/kg.

Purified sodium tetradecyl sulfate was found to have an LD₅₀ of 2g/kg when administered orally by stomach tube as a 25% aqueous solution to rats. In rats given 0.15g/kg in drinking water for 30 days, no appreciable toxicity was seen, although some growth inhibition was discernible.

Manufactured for:
Bioniche Pharma U.S.A. Inc.
Bogart, GA 30622

Manufactured by
Bioniche Teo
Inverin, Co. Galway, Ireland

Issued: October 2004

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BIONICHE CUSTOMER SERVICE 888-258-4199

Bioniche Pharma USA, Bogart, GA 30622 rev.10/04

BIONICHE
PHARMA GROUP LIMITED

SOTRADECOL™
SODIUM TETRADECYL SULFATE INJECTION
EXCLUSIVELY FROM BIONICHE PHARMA GROUP

Dilution Guide for SOTRADECOL™

SOTRADECOL™ 3%, 2 mL Vial

3% solution (2mL) + **0.4 mL diluent** = A final concentration of **2.5%, 2.4 mL**

3% solution (2mL) + **1 mL diluent** = A final concentration of **2%, 3 mL**

3% solution (2mL) + **2 mL diluent** = A final concentration of **1.5%, 4 mL**

3% solution (2mL) + **4 mL diluent** = A final concentration of **1%, 6 mL**

3% solution (2mL) + **6 mL diluent** = A final concentration of **0.75%, 8 mL**

3% solution (2mL) + **10 mL diluent** = A final concentration of **0.5%, 12 mL**

3% solution (2mL) + **22 mL diluent** = A final concentration of **0.25%, 24 mL**

3% solution (2mL) + **28 mL diluent** = A final concentration of **0.2%, 30 mL**

3% solution (2mL) + **58 mL diluent** = A final concentration of **0.1%, 60 mL**

SOTRADECOL™ 1%, 2 mL Vial

1% solution (2mL) + **0.67 mL diluent** = A final concentration of **0.75%, 2.67 mL**

1% solution (2mL) + **2 mL diluent** = A final concentration of **0.5%, 4 mL**

1% solution (2mL) + **6 mL diluent** = A final concentration of **0.25%, 8 mL**

1% solution (2mL) + **8 mL diluent** = A final concentration of **0.2%, 10 mL**

1% solution (2mL) + **18 mL diluent** = A final concentration of **0.1%, 20 mL**



v300 Product Code: Z2001-00

The v300 is our entry level product incorporating the v600 patented cross polarized subsurface technology into an affordable package. Suggested use with sclerotherapy, hair restoration, general surgery or aesthetic filler procedures.

Features and Benefits

- Revolutionary patented cross polarized technology allows the user to see approximately 1mm below the skin's surface.
- The v300 emits a larger, 6 to 8 inch diffused area of light which is preferred by some physicians when used for general dermatology, sclerotherapy and hair restoration.
- Combine this with changeable magnification and you have the complete visualization system for all of your needs.
- Allows user to be hands free during procedures. The reduced glare minimizes stress and eye fatigue. Increased accuracy, reduced procedure time and reduced tissue damage are results that are benefits to the patient and medical professional.



v600 Product Code: Z1924-00

The v600 combines high-powered, color corrected illumination with the highest quality optical filters to produce optimum light density for use with laser goggles during laser procedures. Combine this with changeable magnification and you have the complete Visualization System for all of your needs.

Features and Benefits

- Revolutionary patented subsurface technology allows the user to see approximately 1mm below the skin's surface.
- Combines high powered, color corrected illumination with the highest quality optical filters to produce optimum light density with laser goggles during laser procedures.
- Combine this with changeable magnification and you have the complete visualization system for all of your needs.
- Our patented cross polarization technology literally shows you what's under the skin and allows you superior targeting of telangiectasia and spider veins.



Vantage Product Code: Z3500-01 Floor

Paired with Syris' patented cross polarized technology, magnification; LED lights provides a quality light source. Floor stand or table top options offer a unique level of comfort to the medical professional and patient. Suggested to be used with sclerotherapy, hair restoration, general skin exams with some lasers.

Features

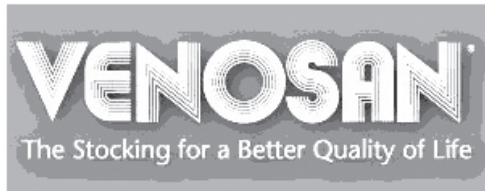
- Revolutionary patented subsurface technology allows the user to see approximately 1mm below the skin's surface.
- Free standing design offers ultimate versatility.
- 5" lens enables easy photo documentation.
- Combine this with magnification and you have the complete visualization system for all of your needs.
- Our patented cross polarization technology literally shows you what's under the skin and allows you superior targeting of tissue.

Benefits

- Excellent for general exams, sclerotherapy and hair transplantations.
- Improved outcomes by eliminating glare and accentuating subsurface structures.
- Superior diagnosis

Photography

- Enhance your practice with photo documentation with your own camera.
- The Vantage provides point and shoot photographic capability for capture of images and for documentation and patient consult.



For more information about Venosan North America,
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Marketing

Visual sclerotherapy is considered a cosmetic procedure and therefore, not insurable. Since it is often, not only associated with medical spas, but a valuable component of a cosmetic practice, advertising can be a very effective means of acquiring patients. Like other cosmetic procedures, word of mouth isn't always the most effective advertising due to the patient's desire to keep body enhancing treatments private. The following are sample advertisements found in various magazines and newspapers. Including before and after pictures is always intriguing and enticing to potential patients.

Other than media advertising, open houses, educational seminars, health fairs and speaking engagements at local clubs have proven to be a very effective form of advertising. Keeping a log of how the patient heard about your practice will enable you to tweak your sources of advertising in order to be the most effective with your budget.

Marketing Tips:

Holding strong in a slow economy

AAI Corporate Meeting
March 18-20, 2010

Ladies always want to look better! Even during the Great Depression, certain industries, called “sin industries”, not only survived, but thrived. These were businesses like cigarettes, alcohol and *beauty*! During those hard financial days, we were introduced to Revlon lipstick, L’Oreal makeup and we made those companies very successful. Hershey also introduced Mr. Goodbar, Krackel bar, and chocolate chips! You get the picture. We are willing to spend money on things that make us feel better about ourselves, especially when the economy is in a downward spiral. If we have *effective* marketing, we can withstand a slow economic period; it has been proven!

1. Advertising

a. Market Specific

Radio/ TV- will it work in my market?

Piggy back on what is featured on national talk shows: Oprah, Today Show, etc

b. What’s a “newspaper? Phonebook?”

These are dying a slow death, beware of high cost and low yield.

c. Print ads

Take advantage of vendors national media campaigns: In Style, New Beauty

“City” magazines are a very targeted market, i.e. Atlanta Magazine.

2. Events

a. Get the Word Out

People have to hear advertising 7 times to remember it.

b. Do’s and Don’ts of Events

Do- have live demos, vendors present, invitations, coupons, door prizes, favors, food, theme

Don’t- assume people will come without advertising, compete with other special events

c. Educational seminars with live demo

The “model” patient must bring pre-determined number of guest (15) to watch the injection and receive prorated discount, depending on number of guest attending. You provide refreshments but have no advertising cost.

3. E-Marketing

In order to have effective e -marketing, you first have to collect email addresses from patients. You should have a note on your pt information form for the patient to sign to receive emails from you.

- a. Newsletter (Constant Contact)
 - Secret Special, coupons, information article, before and after pics
- b. E blast
 - Specials, news alerts
- c. Website
 - Keep current
 - Before and after pictures
 - Information
- d. Blogs
 - Information
- e. Social Networks
 - Facebook, Twitter, Linked In

4. Message

- a. Entice your targeted market
 - Use verbage that they want to hear/ looking for: ie Look better for your high school reunion, mother- of –the – bride, wear shorts this summer.
- b. Stay Real
 - Don't promise things you can't deliver
 - Know what you don't know
- c. Sells or Service
 - Practice retail medicine: the consumer has choices, why choose you?
 - You are the hostess, the example and the provider.
 - Must have "customer service department": return calls promptly, decrease wait times, accommodate schedules.

5. Mailouts/ Cards

- a. Birthday cards, with a freebie
- b. Thank you referrals to patients who refer new patients
- c. Vendors VIP cards, frequent user cards
- d. Rebates

6. Methods/ Venues

- a. Creative bundling: free product with procedure, etc.
- b. Gift with purchase, i.e. Obagi® hats
- c. Social Clubs
 - They are always looking for a place and a speaker. Offer to host a monthly meeting **and** be the speaker; garden clubs, service clubs, etc.

- d. Offer Birthday Luncheons, "Only your Best Friend Knows" luncheon, where 2 or more ladies come in together for consultation and lunch, Power Lunch with Botox® treatment. (We use a local deli that delivers for the lunches.)
- e. Health fairs have proven not to be the best venue for marketing your practice as most people are looking for give aways, not investment in services.



Shop 'til You Drop

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Vein Specialists of the South offers the most advanced and effective surgical and non-surgical treatment for painful varicose veins, leg ulcers & unsightly spider veins.

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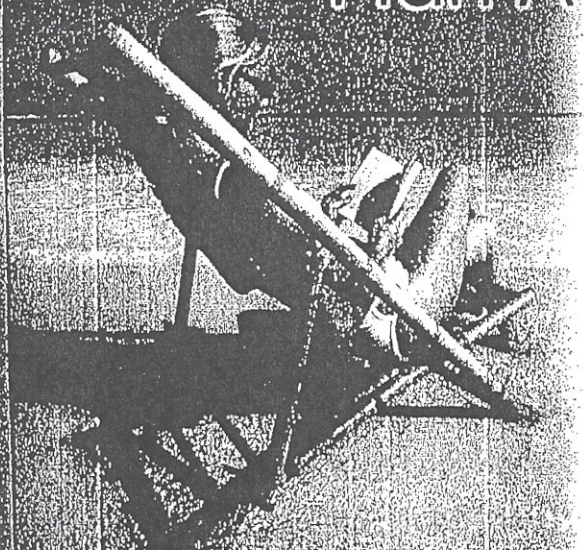
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