

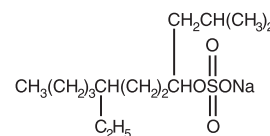
SOTRADECOL® (Sodium tetradecyl sulfate)

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:



C₁₄H₂₉NaSO₄ 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

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Approved by the FDA

SOTRADECOL®

SODIUM TETRADECYL SULFATE

Now Available in the US Market



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PHARMA GROUP LIMITED

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YOUR INJECTABLE SOLUTION

For Information Contact:
Bioniche Customer Service
888-258-4199

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

Sotradecol® (Sodium Tetradecyl Sulfate) Bioniche Pharma Group

Well-Known Molecule in the US Sclerotherapy Market

- ❖ Sodium Tetradecyl Sulfate has been used extensively as the preferred sclerotherapy treatment for a long time.

Sclerosing Solution for small uncomplicated Varicose Veins of lower extremities

- ❖ Sotradecol® by Bioniche Pharma has been approved to be therapeutically equivalent to the innovator (Sotradecol 1% & 3% 2ml vials previously manufactured by ESI).

Now Approved by the FDA

- ❖ FDA-approved Sotradecol® by Bioniche Pharma is now available in the US Market, which guarantees safety compared to compounded forms that may not meet FDA standards and are not guaranteed.

The only commercially available "Sodium Tetradecyl Sulfate" in the US market

- ❖ Sotradecol® is now available through Bioniche directly, as well as, a wide network of distributors, wholesalers and pharmacies for use in both sclerotherapy clinics and hospitals.

Available in Two Strengths; 1% & 3% - 2ml Vials

- ❖ Sotradecol®, available in two strengths, gives greater flexibility to treat varied sizes and magnitudes of Varicose Veins.

IV Injection in 5-Vial (New) Packs

- ❖ Sotradecol® is available in packs of 5 vials to better service patients requiring longer or more extensive course of treatment.

Manufactured in an FDA cGMP-Approved Sterile Facility

- ❖ Sotradecol® is now manufactured by Bioniche Pharma Group Limited that produces both brand name and specialty sterile injectable products for world markets. All our products are manufactured in our IMB (Europe), FDA and Health Canada approved cGMP and ISO 13485-compliant facility, guaranteeing high standards of final "sodium tetradecyl sulfate" formulation and complying with all "public safety" guidelines.

Ready for use at your fingertips

- ❖ Sotradecol® can be ordered by calling the Bioniche Pharma customer service direct line 1(888) 258-4199 or by contacting your local distributor or wholesaler.

Sotradecol® (Sodium Tetradecyl Sulfate) Bioniche Pharma Group

Safer than pharmacy-compounded non-manufactured STS molecules

Offering solution to variety of patients in hospitals and clinics

Therapeutically equivalent to innovator

Right treatment for small uncomplicated Varicose Veins of lower extremities

Approved by FDA

Distributed through wide market network

Efficacy proven

Customer service backup

On-hand delivery at your fingertips

Life quality improved

