Expand Your Practice

Using Sotradecol (Sodium Tetradecyl Sulfate Injection) can help expand your varicose veins practice. By using Sotradecol for the treatment of small uncomplicated varicose veins of the lower extremities that show simple dilation with competent valves, you can expand the treatment options you offer your patients. The benefit-to-risk ratio should be considered in selected patients who are great surgical risks.

- The only FDA approved, commercially available sodium tetradecyl sulfate injection in the US market
- Manufactured to meet the FDA’s quality standards, including sterility, purity, pH and concentration requirements
- Available in two convenient concentrations
  - 1% or 3%
  - 2 ml vials, 5 units/box

**Important Safety Information**

Sotradecol is contraindicated in patients with previous hypersensitivity to the drug; inflammation or incompetence of superficial or deep veins; phlebitis migrans; acute cellulitis; allergic conditions; acute infections; varicocities caused by abdominal and pelvic tumors unless the tumor has been removed; bedridden patients; diabetes; toxic hyperthyroidism; tuberculosis; asthma; neoplasm; sepsis; blood dyscrasias; and acute respiratory or skin diseases.

Due to the risk of deep vein thrombosis, patients should be evaluated for valvular competency and deep venous patency before treatment and slow injections of a small volume (< 2 mL) should be injected. Patients should be monitored post-treatment for deep vein thrombosis and pulmonary embolism. Extreme caution must be exercised in the presence of underlying arterial disease.

Severe adverse local effects, including tissue necrosis, may occur following extravasation; therefore, take care in intravenous needle placement and use the smallest effective volume at each injection site.

Allergic reactions, including fatal anaphylaxis, have been reported. As a precaution, it is recommended that 0.5 mL of Sotradecol be injected, followed by observation for several hours before administration of a second or larger dose. Emergency resuscitation equipment should be immediately available, and the physician prepared to treat an anaphylactic reaction.
At least 6 deaths have been reported. Four of the deaths were cases of anaphylaxis; one in a patient with a history of asthma, a contraindication to Sotradecol use. Another death was in a patient who was taking an anticoagulant agent. One death (pulmonary embolism) occurred in a patient not taking an anticoagulant agent, treated with sodium tetradecyl acetate. Other adverse reactions reported include pulmonary embolism; local injection site reactions (pain, urticaria, ulceration); permanent discoloration of sclerosed vein segment; sloughing and necrosis of tissue following extravasation of the drug; allergic reactions (hives, asthma, hayfever); headache; nausea; and vomiting.

Sotradecol® (Sodium Tetradecyl Sulfate Injection)

FOR INTRAVENOUS USE ONLY

Rx Only

CH3(CH2)11CH(CH3)2

CH3(CH2)11CH(CH3)2

CH2(C2H5)CH2CH2OH

Sodium tetradecyl sulfate is an anionic surfactant which occurs as a white, waxy solid. The structural formula is: C14H29O4S 7-Ethyl-2-methyl-4-hendecanold sodium salt (MW 316.44). Sotradecol (sodium tetradecyl sulfate injection) is a sterile nonpyrogenic solution for intravenous use as a sclerosing agent. 1% 20 mg/mL (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 7.6; monobasic sodium phosphate and/or sodium hydroxide added, if needed, for pH adjustment. 3% 60 mg/mL (30 mg/mL): Each mL contains sodium tetradecyl sulfate 30 mg, benzyl alcohol 0.03 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.

INTERIM CLINICAL PHARMACOLOGY

Sotradecol (sodium tetradecyl sulfate injection) is a sclerosing agent. Intravenous injection causes intima inflammation and thrombus formation. This usually includes 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-risk ratio should be considered in selected patients who are at great surgical risks.

CONTRAINDICATIONS

Sotradecol (sodium tetradecyl sulfate injection) is contraindicated in previous hyperprosanthrombin 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; valvular incompetence; extreme caution must be exercised in the presence of underlying arterial disease such as marked peripheral arteriosclerosis or thromboangiitis obliterans (Buerger’s Disease).

Fear of bleeding and potential for thrombus formation. Extreme caution must be exercised in the presence of underlying arterial disease such as marked peripheral arteriosclerosis or thromboangiitis obliterans (Buerger’s Disease).

Allergic reactions such as hives, asthma, hay fever and anaphylactic shock may occur following extravasation of the drug. (See WARNINGS section).

Sotradecol has been reported to cause fatal systemic reactions (including anaphylaxis) in patients who have 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 anticoagulant 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 mL 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% 20 mg/mL (10 mg/mL)–2 mL vials; in packages of 5 (NDC 65974-162-02)
3% 60 mg/mL (30 mg/mL)–2 mL vials; in packages of 5 (NDC 65974-163-02)

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 2 g/kg when administered orally by stomach tube as a 2% aqueous solution to rats. In rats given 0.15 g/kg in drinking water for 30 days, no appreciable toxicity was seen, although some growth inhibition was discernible.

Manufactured by: Mylan Institutional
Galway, Ireland

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