APPLICATION NUMBER: NDA 5970/S28

FINAL PRINTED LABELING
SOTRADECOL®
(Sodium Tetradecyl Sulfate Injection)
For Intravenous Use Only

DESCRIPTION
Sodium tetradecyl sulfate is an anionic surfactant which occurs as a white, waxy solid. 7-Ethyl-2-methyl-4-
heptadecanol sulfate sodium salt:

Sotradecol® (Sodium Tetradecyl Sulfate Injection) is a sterile nonepigenic solution for intravenous use as a
sclerosing agent. Each mL contains sodium tetradecyl sulfate 10 mg or 30 mg, benzyl alcohol 0.02 mL, and dibasic
sodium phosphate, anhydrous 0.72 mg in Water for injection. pH: 7.0-8.1; monobasic sodium phosphate and/or
sodium hydroxide added, if needed, for pH adjustment.

CLINICAL PHARMACOLOGY
Sotradecol® (sodium tetradecyl sulfate) is a mild sclerosing agent. Intravenous injection causes intimal
inflammation and thrombus formation. This usually includes the injected vein. Subsequent formation of fibrous
tissue results in partial or complete vein obliteration.

INDICATIONS AND USAGE
Indicated in the treatment of small uncomplicated varicose veins of the lower extremities that show simple dilatation
with competent valves. The benefit-to-risk ratio should be considered in selected patients who are great surgical
risks due to conditions such as old age.

CONTRAINDICATIONS
Contraindicated in previous hypersensitivity reactions to the drug; in acute superficial thrombophlebitis;
significant valvular or deep vein incompetence; huge superficial veins with wide open communications to deeper
veins; phlegmasia migrans; acute cellulitis; allergic conditions; acute infections; varicose veins caused by abdominal
and pelvic tumors unless the tumor has been removed; bedridden patients, such as uncontrolled systemic diseases
as diabetes, toxic hyperthyroidism, tuberculosis, asthma, neoplasms, sepsis, blood dyscrasias and acute
respiratory or skin diseases.

WARNINGS
Since severe adverse local effects, including tissue necrosis, may occur following extravasation, Sotradecol®
(Sodium Tetradecyl Sulfate Injection), should be administered only by a physician familiar with proper injection
technique. Extreme care in needle placement and using the minimal effective volume at each injection site are,
therefore, important.

Allergic reactions have been reported. Therefore, as a precaution against anaphylactoid 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 anaphylactoid reaction should be kept in
mind, and the physician should be prepared to treat it appropriately. In extreme emergencies, 0.25 mL of 1:1000
Epinephrine injection (0.25 mg) intravenously should be used and side reactions controlled with antihistamines.

PRECAUTIONS
GENERAL
Venous sclerotherapy should not be undertaken if tests such as the Trendelenberg and Perthes, and angiography
show significant venular or deep venous incompetence. The physician should bear in mind the fact that injection
necrosis is likely to result from extravascular injection of sclerosing agents.

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

The drug should only be administered by physicians who are familiar with an acceptable injection technique.

Because of the danger of thrombosis extending into the deep venous system, thorough preinjection evaluation for
venular 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. In particular, deep venous patency must be determined by
angiography and/or the Perthes test before sclerotherapy is undertaken.
Embolism may occur as much as four weeks after injection of sodium tetradecyl sulfate.

The incidence of recurrence is low if the patient wears elastic stockings.

DRUG INTERACTIONS
No well-controlled studies have been performed on patients taking anticoagulant agents. The physician must use judgment and evaluate any patient taking anticoagulant drugs prior to initiating treatment with Sotradecol® (sodium tetradecyl sulfate). (See ADVERSE REACTIONS.) No interaction should be included in the same syringe as Sotradecol® since the two are incompatible.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY
When tested in the LS178T TK− 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. Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. There are no well-controlled studies in pregnant women, but investigational and marketing experience does not include any positive evidence of adverse effects on the fetus. Although there is no clearly defined risk, such experience cannot exclude the possibility of intrauterine or subtle damage to the human fetus.

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 sodium tetradecyl sulfate injection is administered to a nursing woman.

ADVERSE REACTIONS
Local reactions consisting of pain, urticaria or ulceration may occur at the site of injection. A permanent discoloration, usually small and hardly noticeable but which may be objectionable from a cosmetic viewpoint, may remain along the path of the atherosclerotic vein segment. Sloughing and necrosis of tissue may occur following extravasation of the drug.

Systemic reactions, except for allergic ones, have been slight. These include headache, nausea and vomiting. Allergic reactions such as hives, asthma, hay fever and anaphylactic shock have been reported. (See WARNINGS.)

One death has been reported in a patient who received Sotradecol® (sodium tetradecyl sulfate) and who had been removing an aneurysm with a device.

Another death (fatal pulmonary embolism) has been reported in a 36-year-old female treated with sodium tetradecyl acetate and who was being treated with oral contraceptives.

DOSEAGE AND ADMINISTRATION
For intravenous use only. Do not use if precipitated or discolored. The strength of solution required depends on the size and degree of occlusion. In general, the 4% solution will be found most useful with the 3% solution reserved for larger occlusions. 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.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED
Sotradecol® (Sodium Tetradecyl Sulfate Injection)
1%—2 mL DOSSET® ampule packaged in 5s (NDC 0641-1514-01)
3%—2 mL DOSSET® ampule packaged in 5s (NDC 0641-1515-01)

STORAGE
Store at controlled room temperature 15°–30°C (59°–86°F).

ANIMAL TOXICOLOGY
The intravenous LD₅₀ of sodium tetradecyl sulfate in mice was reported to be 90 to 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 25% 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.

Additional package inserts may be obtained by contacting the Professional Services Department.

Revised April 1987

Manufactured by
ELKINS-SINW, INC., Cherry Hill, NJ 08034-4000
A subsidiary of A.H. Robins Company
SOTRADECOL® 1%
(SODIUM TETRADECYL SULFATE INJECTION)

FOR INTRAVENOUS USE ONLY

Each mL contains sodium tetradecyl sulfate 10 mg, benzyl alcohol 0.02 mL and dibasic sodium phosphate, anhydrous 0.72 mg in Water for Injection, pH 7.0-8.1; monobasic sodium phosphate and/or sodium hydroxide added, if needed, for pH adjustment.

WARNING: Do not use if precipitated.

USUAL DOSE: See package insert.

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

To open ampul, ignore color line; break at constriction.

Caution: Federal law prohibits dispensing without prescription.

Product Code: 1514-34
B-41514b

ELKINS-SINN, INC. Cherry Hill, NJ 08034-4099

2 mL DOSETTE® AMPUL
SOTRADECOL®
(SODIUM TETRADECYL
SULFATE INJECTION)
FOR IV USE ONY
DO NOT USE IF PRECIPITATED

LOT 0036900
EXP. 06/00
ELKINS-SINN, INC.
CHERRY HILL, NJ 08034
Sotradecol® (Sodium Tetradecyl Sulfate Injection)

SOTRADECOL® 3% (SODIUM TETRADECYL SULFATE INJECTION)
FOR INTRAVENOUS USE ONLY
Each mL contains sodium tetradecyl sulfate 30 mg, benzyl alcohol 0.02 mL, and dibasic sodium phosphate, anhydrous 0.72 mg in Water for Injection, pH 7.0-8.1; monobasic sodium phosphate and/or sodium hydroxide added, if needed, for pH adjustment.

WARNING: Do not use if precipitated.

USUAL DOSE: See package insert.

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

To open ampul, ignore color line; break at constriction.

Caution: Federal law prohibits dispensing without prescription.

Product Code: 1518-34  B-41516b

ELKINS-SINN, INC. Cherry Hill, NJ 08003-4099