CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S22

FINAL PRINTED LABELING

Labeling: OTC
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J-1514d APPROVED MAY 05 1977 Revised Sept. 1976

SOTRADECOL

(Sodium Tetradecyl Sulfate)
For Intravenous Use Only

DESCRIPTION
Sotradecol (sodium tetradecyl sulfate) injection is a sterile solution containing in each ml sodium tetradecyl sulfate 10 mg (1%) or 30 mg (3%) in Water for Injection with 0.02 ml benzyl alcohol and buffered with dibasic sodium phosphate; pH is adjusted to 7-8.1 with monobasic sodium phosphate or sodium hydroxide.

ACTIONS
The product is a mild sclerosing agent which acts by irritation of the vein intimal endothelium.

INDICATIONS
Indicated in the treatment of small uncomplicated varicose veins of the lower extremities. 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 acute superficial thrombophlebitis; underlying arterial disease; varicosities caused by abdominal and pelvic tumors, uncontrolled diabetes mellitus, thyrotoxicosis, tuberculosis, neoplasms, asthma, sepsis, blood dyscrasias, acute respiratory or skin diseases; and any condition which causes the patient to be bedridden. Do not use if precipitated.

WARNINGS
Sotradecol (sodium tetradecyl sulfate) should be used in pregnant women only when clearly needed. See Precautions.

PRECAUTIONS
For varicosities, sclerotherapy should not be undertaken if tests such as the Trendelenberg and Perthes, and angiography show significant valvular or deep venous incompetence. The physician should bear in mind the fact that injection necrosis may result from direct injection of sclerosing agents.

The drug should be administered by physicians who are familiar with an acceptable injection technique. Because of the danger of extension of thrombosis into the deep venous system, thorough pre-injection 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. In particular, deep venous patency must be determined by angiography and/or the Perthes test before sclerotherapy is undertaken.

No well controlled studies have been performed on patients taking anti-ovulatory agents. The physician must use judgment and evaluate any patient taking anti-ovulatory drugs prior to initiating treatment with Sotradecol (sodium tetradecyl sulfate). See Adverse Reactions.

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 infrequent or subtle damage to the human fetus.

ADVERSE REACTIONS
Post-operative complication of sloughing may occur. A permanent discoloration, usually small and hardly noticeable may occur at the site of injection, and may be objectionable from a cosmetic viewpoint. Allergic reactions have been reported. Therefore, as a precaution against anaphylactic shock, it is recommended that an injection of 0.5 ml of the product into a varicosity be followed by observance of the patient for several hours before a larger injection is administered. The possibility of an anaphylactic reaction should be kept in mind, and the physician should be prepared to treat it appropriately. In extreme emergencies, 0.25 ml of a 1:1000 solution of epinephrine (0.25 mg) intravenously should be used and side reactions controlled with antihistamines.

One death has been reported in a patient who received Sotradecol (sodium tetradecyl sulfate) and who had been receiving an anti-ovulatory 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
For intravenous use only. Do not use if precipitated. The strength of solution required depends on the size and degree of varicosity. In general, the 3% solution will be found most useful with the 1% solution preferred for small varicosities. The dosage should be kept small, using 0.5 to 2 ml for each injection, and the maximum single treatment should not exceed 10 ml.

Literature describing various current techniques of administration is available upon request from the Technical Services Department.

HOW SUPPLIED
1% – 2 ml Dosette® Ampuls, 5's – #341514 (*NDC* 0641-1514-34)

3% – 2 ml Dosette® Ampuls, 5's – #341516 (*NDC* 0641-1516-34)

CAUTION: Federal law prohibits dispensing without prescription.

Manufactured by

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