

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 5970/S18**

**FINAL PRINTED LABELING**

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## **SOTRADECOL®**

(Sodium Tetradecyl Sulfate)  
FOR INTRAVENOUS USE ONLY

### **DESCRIPTION**

A sterile solution containing 1% or 3% Sodium Tetradecyl Sulfate. It is an aqueous solution with 2% Benzyl Alcohol, buffered with Disodium Phosphate and adjusted with Sodium Dihydrogen Phosphate or Sodium Hydroxide to a pH of 7 to 8.1.

### **ACTIONS**

The product is a mild sclerosing agent for varicose veins. It produces a penetrating but not diffused, internal irritation.

### **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 dyscrasia, acute respiratory or skin diseases; and any condition which causes the patient to be bed-ridden. Do not use if precipitated.

### **WARNINGS**

This product is not recommended for treatment of varicose veins during pregnancy.

### **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 infection 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.

Anti-ovulatory drugs should be discontinued prior to initiating Sotradecol® therapy.

#### **ADVERSE REACTIONS**

Postoperative 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 1/2 ml of the product into a varicosity be followed by observance of the patient for several hours before more extensive injection is administered. The possibility of an anaphylactic reaction should always 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.

#### **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 1/2 to 2 ml for each injection, and the maximum single treatment should not exceed 10 ml.

#### **HOW SUPPLIED**

- 1% Sterile solution:  
2 ml. DOSETTE® Ampuls
- 3% Sterile solution:  
2 ml. DOSETTE® Ampuls

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