CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S13

FINAL PRINTED LABELING

SUPPLEMENT - JUNE 30, 1972
NDA 5-970, S-010
SOTRADECOL (SODIUM TETRADECYL SULFATE)

NDA No: 5970 Rc'd. 7-5-72
Reviewed by: C. Monnel 8/28/72

SECTION 4. COPIES OF LABELS AND LABELING

AMPUL LABEL SCREEN 1% AND 3%
BOX LABEL 1% AND 3%

2 ml DOSETTE® AMPUL
SOTRADECOL®
SODIUM TETRADECYL SULFATE 1%
FOR I.V. USE ONLY
DO NOT USE IF PRECIPITATED
KA-1514
ELKINS SINN INC.
CHERRY HILL, N.J. U.S.A.
LOT NO. 00000

SEP 14 1972 approved

2 ml DOSETTE® AMPUL
SOTRADECOL®
SODIUM TETRADECYL SULFATE 3%
FOR I.V. USE ONLY
DO NOT USE IF PRECIPITATED
KA-1516
ELKINS SINN INC.
CHERRY HILL, N.J. U.S.A.
LOT NO. 00000

approved SEP 14 1972

SOTRADECOL 1%

Open at perforation —slide tray out

NDC 641-1514-33

10 DOSETTE® Ampuls

Each contains 2 ml.

SOTRADECOL® 1%

brand of SODIUM TETRADECYL SULFATE

FOR INTRAVENOUS USE ONLY

An aqueous solution with 2% Benzyl Alcohol, buffered with Disodium Phosphate, and adjusted with Sodium Dihydrogen Phosphate or Sodium Hydroxide to pH of 7.0 to 8.1.

Warning: Do not use if precipitated.

Read Enclosed Directions Before Using

SEP 14 1972 approved

Caution: Federal law prohibits dispensing without prescription.

Product code 331514

B-31514

SOTRADECOL 1% SODIUM TETRADECYL SULFATE

1%

ESI ELKINS-SINN, INC. Cherry Hill, N.J. 08002 U.S.A.

1%

SOTRADECOL 3%

10 DOSETTE® Ampuls

NDC 641-1516-33

Open at perforation —slide tray out

Each contains 2 ml.

SOTRADECOL® 3%

brand of SODIUM TETRADECYL SULFATE

FOR INTRAVENOUS USE ONLY

An aqueous solution with 2% Benzyl Alcohol, buffered with Disodium Phosphate, and adjusted with Sodium Dihydrogen Phosphate or Sodium Hydroxide to pH of 7.0 to 8.1.

Warning: Do not use if precipitated.

Read Enclosed Directions Before Using

SEP 14 1972 approved

Caution: Federal law prohibits dispensing without prescription.

Product code 331516

B-31516

SOTRADECOL 3% SODIUM TETRADECYL SULFATE

3%

ESI ELKINS-SINN, INC. Cherry Hill, N.J. 08002 U.S.A.

3%

Lot Number will be stamped on each immediate label.

Labeling: Orig

NDA No: 5970 Rc'd. 7-5-72

Reviewed by: C. Monroe 8/28/72

SUPPLEMENT - June 30, 1972
NDA 5-970, S-010 and S-013
SOTRADECOL (SODIUM TETRADECYL SULFATE)

SECTION 4. COPIES OF LABELS AND LABELING

ESI PACKAGE INSERT

Revised May, 1972

J-1156

SOTRADECOL®

(Sodium Tetradecyl Sulfate)
FOR INTRAVENOUS USE ONLY

CM

DESCRIPTION
For intravenous use only. 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 itrritation.

INDICATIONS
Indicated in the treatment of small uncomplicated varicose veins of the lower extremeties. 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 bedridden. Do not use if precipitated.

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

PRECAUTIONS
For varicosities, sclerotherapy should not 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 ½ 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
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 ½ to 2 ml for each injection, and the maximum single treatment should not exceed 10 ml.

HOW SUPPLIED
1% Sterile solution:
10 ml. Multiple Dose Vials
2 ml. DOSETTE® Ampuls
3% Sterile solution:
10 ml. Multiple Dose Vials
2 ml. DOSETTE® Ampuls

ELKINS-SINN, INC, Cherry Hill, N.J., U.S.A.