

DRUG INTERACTIONS

No well-controlled studies have been performed on patients taking antiovolatory agents. The physician must use judgment and evaluate any patient taking antiovolatory drugs prior to initiating treatment with Sotradecol®. (See ADVERSE REACTIONS section).

Heparin should not be included in the same syringe as Sotradecol®, since the two are incompatible.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

When tested in the L5178YTK +/- 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. Animal reproduction studies have not been conducted with Sotradecol®. It is also not known whether Sotradecol® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sotradecol® should be given to a pregnant woman only if clearly needed and the benefits outweigh the risks.

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 Sotradecol® is administered to a nursing woman.

PEDIATRIC USE

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Local reactions consisting of pain, urticaria or ulceration may occur at the site of injection. A permanent discoloration may remain along the path of the sclerosed vein segment. Sloughing and necrosis of tissue may occur following extravasation of the drug. (See WARNINGS section).

Allergic reactions such as hives, asthma, hayfever and anaphylactic shock have been reported. Mild systemic reactions that have been reported include headache, nausea and vomiting. (See WARNINGS section).

At least six deaths have been reported with the use of Sotradecol®. Four cases of anaphylactic shock leading to death have been reported in patients who 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 antiovolatory agent. Another death (fatal pulmonary embolism) has been reported in a 36-year-old female treated with sodium tetradecyl sulfate 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 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% (10 mg/mL) - 2 mL vials; in packages of 5 (NDC 67457-162-02)

3% (30 mg/mL) - 2 mL vials; in packages of 5 (NDC 67457-163-02)

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 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.

Manufactured for:

Bioniche Pharma U.S.A. LLC.

Lake Forest, IL 60045

Manufactured by

Bioniche Teo

Inverin, Co. Galway, Ireland

Issued: October 2004

Revised: February 2008

0521L104