PRESCRIBING INFORMATION

Trombojet® 1% (10 mg / mL)

and

Trombojet® 3% (30 mg / mL)

Sodium Tetradecyl Sulfate

Omega Standard

FOR INTRAVENOUS USE ONLY

Sclerosing Agent

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PART I: HEALTH PROFFESIONAL INFORMATION

1. INDICATIONS

Tromboject® 1% and Tromboject® 3% are indicated for:

- the treatment in adults of varicose veins of the legs by compression sclerotherapy.

Sodium tetradecyl sulfate causes a direct irritation of the intima and formation of a thrombus, while compression promotes the occlusion of the vein by fibrosis.

2. CONTRAINDICATIONS

Tromboject® 1% and Tromboject® 3% (sodium tetradecyl sulfate injection) are contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredients, or component of the container. For a complete listing, see **5. DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.**

Tromboject® 1% and Tromboject® 3% are also contraindicated in the following cases:

- Acute superficial trombophlebitis
- Valvular or deep vein incompetence
- Huge superficial veins with wide open communications to deeper veins
- Phlebitis migrans
- Acute cellulitis
- Allergic conditions
- Acute infections; local infection in the area of sclerotherapy or severe systemic infection
- Varicosities caused by abdominal and pelvic tumors unless the tumor has been removed
- Bedridden patients, long-lasting immobility
- Uncontrolled or poorly controlled systemic diseases such as diabetes, toxic hyperthyroidism, tuberculosis, asthma, neoplasm, sepsis, blood dyscrasias and acute respiratory or skin diseases

3. DOSAGE AND ADMINISTRATION

Tromboject® 1% and Tromboject® 3% (sodium tetradecyl sulfate injection) are for intravenous (IV) use only.

The concentration to be used and the dosage range depend on the size and length of the veins to be treated.

Recommended adult doses:

- Small veins: 0.5 to 2 mL of the 1% (10 mg/mL) solution per injection.
- Medium or large veins: 0.5 to 2 mL of the 3% (30 mg/mL) solution per injection.

The maximum volume injected in a single treatment session should not exceed 10 mL.

The lowest possible volume (preferably 1 mL maximum for each injection) is to be injected slowly by the IV route. Allow a 5-cm spacing between injection sites. The recommended interval between treatments is usually 5-7 days.

4. OVERDOSAGE

Please see **6. WARNINGS AND PRECAUTIONS**.

For management of a suspected drug overdose, contact your regional poison control centre.

5. DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Product	Dosage Form / Strength/Composition	Non-medicinal Ingredients	Route of Administration
Trombojet® 1% (2 mL vial)	Sterile solution 1% (20 mg/2 mL) Each mL contains: Sodium tetradecyl sulfate (10 mg)	Each mL contains: Benzyl alcohol (20 mg) Phosphoric acid (for pH adjustment) Sodium phosphate dibasic, anhydrous (1.19 mg) In water for injection (Q.S.)	Intravenous
Trombojet® 3% (2 mL vial)	Sterile solution 3% (60 mg/2 mL) Each mL contains: Sodium tetradecyl sulfate (30 mg)		
Trombojet® 3% (5 mL vial)	Sterile solution 3% (150 mg/5 mL) Each mL contains: Sodium tetradecyl sulfate (30 mg)		

Tromboject® 1% is available in boxes of 10 x 2 mL multidose vials.
Tromboject® 3% is available in boxes of 10 x 2 mL multidose vials and boxes of 5 x 5 mL multidose vials.

6. WARNINGS AND PRECAUTIONS

General

Tromboject® 1% and Tromboject® 3% (sodium tetradecyl sulfate injection) should only be administered by a healthcare professional experienced in venous anatomy and the diagnosis and treatment of conditions affecting the venous system and familiar with proper injection technique. Severe adverse local effects, including tissue necrosis, may occur following extravasation. Inadvertent intra-arterial injection could cause extended tissue necrosis and its sequelae. Therefore, extreme care in intravenous needle placement and using the minimal effective volume at each injection site are important.

Emergency resuscitation equipment should be immediately available. Allergic reactions, including fatal anaphylaxis, have been reported. As a precaution against anaphylactic shock, it is recommended that 0.5 mL of Tromboject® 1% or Tromboject® 3% 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 anaphylactic reaction should be kept in mind, and the physician should be prepared to treat it appropriately.

Because of the danger of thrombosis extension into the deep venous system, thorough preinjection evaluation for vascular 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. Deep venous patency must be determined by noninvasive testing such as duplex ultrasound. Venous sclerotherapy should not be undertaken if tests such as Trendelenberg and Perthes, and angiography show significant valvular or deep venous incompetence.

The development of deep vein thrombosis and pulmonary embolism have been reported following sclerotherapy treatment of superficial varicosities. Patients should have post-treatment follow-up of sufficient duration to assess for the development of deep vein thrombosis. Embolism may occur as long as four weeks after injection of sodium tetradecyl sulfate. Adequate post-treatment compression may decrease the incidence of deep vein thrombosis.

Extra caution should be exercised in patients considered to be at higher risk of thromboembolic events. In such cases, Tromboject® 1% and Tromboject® 3% should only be used if the benefits clearly outweigh the risks.

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

Arterial Embolism

Stroke, transient ischemic attack, myocardial infarction, and impaired cardiac function have been reported in close temporal relationship with sodium tetradecyl sulfate administration. These events may be caused by air embolism when using the product foamed with room air (high nitrogen concentration) or thromboembolism. The safety and efficacy of sodium tetradecyl sulfate foamed with room air have not been established so the use of foamed product should be avoided.

6.1 Special Populations

6.1.1 Pregnant Women

Animal reproduction studies have not been conducted with Tromboject® 1% and Tromboject® 3%. It is also not known whether Tromboject® 1% and Tromboject® 3% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Tromboject® 1% and Tromboject® 3% should be given to a pregnant woman only if clearly needed and the benefits outweigh the risks.

6.1.2 Breast-feeding

It is not known whether Tromboject® 1% and Tromboject® 3% are excreted in human milk. Precaution should be exercised because many drugs can be excreted in human milk.

6.1.3 Pediatrics

No data available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7. ADVERSE REACTIONS

Local reactions consisting of pain, phlebitis, urticaria or ulceration may occur at the site of injection. A temporary or permanent discoloration (hyperpigmentation) may remain along the path of the sclerosed vein segment. Sloughing and necrosis of tissue may occur following extravasation of the drug. (See **6. WARNINGS AND PRECAUTIONS**). The risks of hyperpigmentation and tissue necrosis may be increased when a higher concentration of drug is used.

Allergic reactions such as hives, asthma, hay fever and anaphylactic shock have been reported. Mild systemic reactions that have been reported include headache, nausea and vomiting. (See **6. WARNINGS AND PRECAUTIONS**.)

At least six deaths have been reported with the use of sodium tetradecyl sulfate injection. Four of these deaths were associated with cases of anaphylactic shock reported in patients who received sodium tetradecyl sulfate injection. One of these four patients reported a history of asthma; uncontrolled or poorly controlled asthma is a contraindication to the administration of Tromboject® 1% and Tromboject® 3%. (See **2. CONTRAINDICATIONS** and **6. WARNINGS AND PRECAUTIONS**). The fifth death has been reported in a patient who received sodium tetradecyl sulfate injection and who had been receiving an antiovulatory agent. The sixth 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.

Cerebrovascular accident, myocardial infarction, deep vein thrombosis.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

8. DRUG INTERACTIONS

No well-controlled studies have been performed on patients taking antiovulatory agents. The physician must use judgement and evaluate any patient taking antiovulatory drugs prior to initiating treatment with Tromboject® 1% or Tromboject® 3%. (See **7. ADVERSE REACTIONS**)

Heparin should not be included in the same syringe as Tromboject® 1% and Tromboject® 3%, since the two are incompatible.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

9. STORAGE

Store at room temperature (15 - 30°C); protect from light. The injection should not be used if it contains a precipitate.

10. SUPPORTING PRODUCT MONOGRAPHS

1. Sotradecol® (Sodium Tetradecyl Sulfate Injection); 1% 20 mg/mL (10 mg/mL) and 3% 60 mg/2 mL (30 mg/mL); SPL Document; Mylan Institutional LLC; October 2, 2019. (US FDA ANDA040541).