

# Tromboject®

1% and 3%

**Sodium Tetradecyl Sulfate, Omega Standard  
Sclerosing agent — I.V. only**

## DESCRIPTION:

Sterile sclerosing solution of Sodium Tetradecyl Sulfate to be used intravenously for the treatment of varicose veins.

TROMBOJECT® 1%: 10 mg/mL

TROMBOJECT® 3%: 30 mg/mL

## INDICATIONS:

TROMBOJECT® is primarily used in the treatment 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.

## CONTRAINDICATIONS:

Strictly contraindicated, as any sclerosing agent, in case of:

- recent superficial or deep thrombophlebitis (6 months to 2 years)
- varicose veins caused by abdominal or pelvic tumors
- potential underlying arterial disease
- renal or cardiac insufficiencies accompanied by venous stasis and dilatation
- angina pectoris
- local or systemic infections
- hyperthyroidism
- uncontrolled diabetes mellitus
- asthma

Do not administer to patients with a history of sodium tetradecyl sulfate hypersensitivity.

## ADVERSE EFFECTS:

Allergic reactions such as malaise, urticaria, angioneurotic edema, have been reported rarely. Anaphylactic reactions may exceptionally occur.

Local reactions, such as pain and necrosis, may appear in case of extravasation.

## PRECAUTIONS:

Due to the risk of necrosis or sloughing following extravasation, TROMBOJECT® should be used only under strict medical supervision, preferably by a physician accustomed to the sclerotherapy technique.

Thrombosis induced by sodium tetradecyl sulfate may extend to the deep venous system, particularly in patients with marked valvular incompetency. Consequently, it is essential to assess the valvular competency, deep vein patency and deep vein competency by angiography and / or test as the Perthes test or the Trendelenberg test, before undertaking treatment.

Although the risk for the patient to develop an allergic reaction is slight, it is advisable to inject 0.3 mL of the 10 mg/mL solution into a varicose vein and to keep the patient under observation during several hours before administering a more significant quantity. The physician has to make sure adequate facilities for the treatment of anaphylactic reactions are available, particularly 1:1000 epinephrine solution (0.25 mL injections) and antihistamines.

A pigmentation may occur at the injection site in case of overdosage.

Safety for use in pregnancy has not been established. Use only when clearly needed and when the potential benefits outweigh the potential hazards to the foetus.

It is not known whether sodium tetradecyl sulfate is excreted in human milk. Caution should be exercised when used in nursing mothers.

## DOSAGE:

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

**Usual doses:**

Small veins: 0.5 to 2 mL of the 10 mg/mL solution  
Medium or large veins: 0.5 to 2 mL of the 30 mg/mL solution

**The smaller possible volume** has to be injected, **slowly** and by the **I.V. route**.  
**Do not inject more than 2 mL of either concentration into a single varicosity; respect a 5 cm interval between two injection sites.**

**Do not inject more than 3 mL of the 30 mg/mL solution per visit.**

The recommended interval between treatments is usually 5-7 days.

**SUPPLIED:**

Boxes of 10 x 2 mL vials (1% and 3%)

Boxes of 5 x 5 mL vials (3% only)

**Contains:**

TROMBOJECT® ..... 1%  
Sodium tetradecyl sulfate, Omega Standard: 10 mg/mL

TROMBOJECT® ..... 3%  
Sodium tetradecyl sulfate, Omega Standard: 30 mg/mL

Each vial also contains:

Benzyl alcohol: 20 mg/mL

Phosphate buffer at pH 7.6, and Water for Injection, q.s.

**Store at room temperature (15 - 30°C);**

**protect from light.**

**The injection should not be used if it contains a precipitate.**

