ASCLERA

INDICATIONS

Asclera® (polidocanol) is indicated to sclerose uncomplicated spider veins (varicose veins <1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremity. Asclera has not been studied in varicose veins more than 3 mm in diameter.

WARNINGS AND PRECAUTIONS

Asclera is contraindicated for patients with known allergy to polidocanol and patients with acute thromboembolic diseases. Severe allergic reactions have been reported following polidocanol use, including potentially fatal anaphylactic reactions. Severe reactions are more frequent with use of larger volumes (> 3 ml). Minimize the dose of polidocanol. Be prepared to treat anaphylaxis appropriately.

Venous Thrombosis and Pulmonary Embolism: Asclera can cause venous thrombosis and subsequent pulmonary embolism or other thrombotic events. Follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent major surgery (within 3 months), prolonged hospitalization, or pregnancy are at increased risk for developing thrombosis.

Arterial Embolism: Stroke, transient ischemic attack, myocardial infraction, and impaired cardiac function have been reported in close temporal relationship with polidocanol 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 polidocanol foamed with room air has not been established and its use should be avoided.

Tissue Ischemia and Necrosis: Intra-arterial injection or extravasation of polidocanol can cause severe necrosis, ischemia or gangrene. Take care in intravenous needle placement and use the smallest effective volume at each injection site. After the injection session is completed, apply compression with a stocking or bandage and have patients walk for 15-20 minutes. If intra-arterial injection of polidocanol occurs, consult a vascular surgeon immediately. Maintain compression for 2 to 3 days after treatment of spider veins and for 5 to 7 days for reticular veins. For extensive varicosities, longer compression treatment with compression bandages or a gradient compression stocking of a higher compression class is recommended. Post-treatment compression is necessary to reduce the risk of deep vein thrombosis.

ADVERSE REACTIONS

In clinical studies, the following adverse reactions were observed after using Asclera and were more common with Asclera than placebo: injection site hematoma, injection site irritation, injection site discoloration, injection site pain, injection site pruritus, injection site warmth, neovascularization, injection site thrombosis.

POST-MARKETING SAFETY EXPERIENCE

The following adverse reactions have been reported during use of polidocanol in world-wide experience. Because these reactions are reported voluntarily from a population of uncertain size and without a control group, it is not possible to estimate their frequency reliably or to establish a causal relationship to drug exposure.

Immune system disorders: Anaphylactic shock, angioedema, generalized urticaria, asthma. **Nervous system disorders:** Cerebrovascular accident, migraine, paresthesia (local), loss of consciousness, confusional state, dizziness. **Cardiac disorders:** Cardiac arrest, palpitations. **Vascular disorders:** Deep vein thrombosis, pulmonary embolism, syncope vasovagal, circulatory collapse, vasculitis. **Respiratory, thoracic, and mediastinal disorders:** Dyspnea. **Skin and subcutaneous tissue disorders:** Skin hyperpigmentation, allergic dermatitis, hypertrichosis (in the area of sclerotherapy). **General disorders and injection site conditions:** Injection site necrosis, pyrexia, hot flush. **Injury, poisoning, and procedural complications:** Nerve injury.

You are encouraged to report any suspected adverse events. To report SUSPECTED ADVERSE REACTIONS, contact your Healthcare Provider, Methapharm Medical Information at 1-866-701-4636, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Please see Full Prescribing Information available at www.asclera.com. For more information please call 1-833-766-8346 (VEIN).

REFERENCES

1. Asclera® Full Prescribing Information. Methapharm, Inc., 2022 **2.** Rabe E, Schliephake D, Otto J, Breu F, Pannier F. Sclerotherapy of telangiectases and reticular veins: a double-blind, randomized, comparative clinical trial of polidocanol, sodium tetradecyl sulphate and isotonic saline (EASI study). *Phlebology*. Jun 2010;25(3): 124-131. **3.** Mann MS, Munavalli, GS, Amatangelo LS, Morrison NS. Improper potency and impurities in compounded polidocanol *JDD*. 2019;18(11): 1124-1127.

methapharm
Specialty Pharmaceuticals

Copyright © 2023 Methapharm, Inc. All rights reserved. Asclera® is a registered trademark of Chemische Fabrik Kreussler & Co. GmbH. Distributed by Methapharm, Inc.

Results matter.

Asclera® (polidocanol) Injection is a prescription medication approved by the FDA for the treatment of spider veins (≤ 1 mm in diameter) and reticular veins (1-3 mm in diameter) in the lower extremities.[1] It is used in a treatment called sclerotherapy. Asclera is injected into an affected vein causing it to seal shut and eventually reabsorb into the body. The affected veins fade from view over time. Clinical studies have shown that 88% of patients are satisfied or very satisfied with Asclera treatment.[2]

Spider veins treated with 0.5% Asclera

Reticular veins treated with 1.0% Asclera

The ampule graphic displayed above is a design concept that has not been approved for distribution.

Visit www.asclera.com for more information.

Study Design

Asclera was evaluated in a multi-center, randomized, double-blind, placebo and comparator-controlled trial (EASI-study).[2]

Patients received one of the following (N = 388):

- Asclera 0.5% for spider veins (n = 94), Asclera 1% for reticular veins (n = 86)
- Sodium tetradecyl sulfate (STS) 1% (n = 105) for either spider or reticular veins
- Placebo (0.9% isotonic saline solution) (n = 53) for either spider or reticular veins

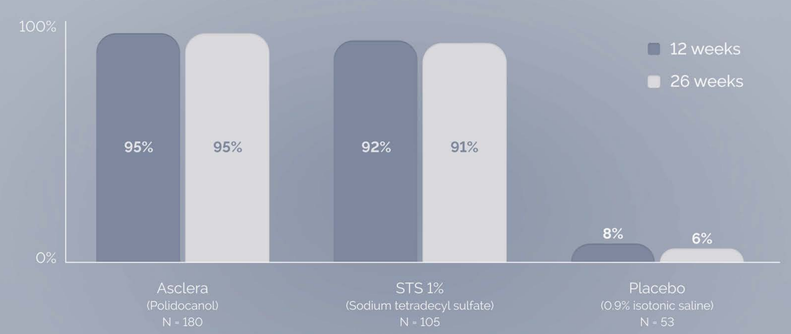
Methodology

Treatment 1: Intravenous injection of Asclera, comparator, or placebo.

Treatment 2 and 3: If Treatment 1 was unsuccessful (defined as 1, 2, or 3 on a 5-point scale), additional treatments were given 3 & 6 weeks later.

Patients returned at 12 & 26 weeks after last injection for final assessments.

Treatment Success



Treatment success was rated by a blinded panel on a 5-point scale (1 = worse than before, 2 = same as before, 3 = moderate improvement, 4 = good improvement, 5 = complete treatment success).

Compounded Polidocanol

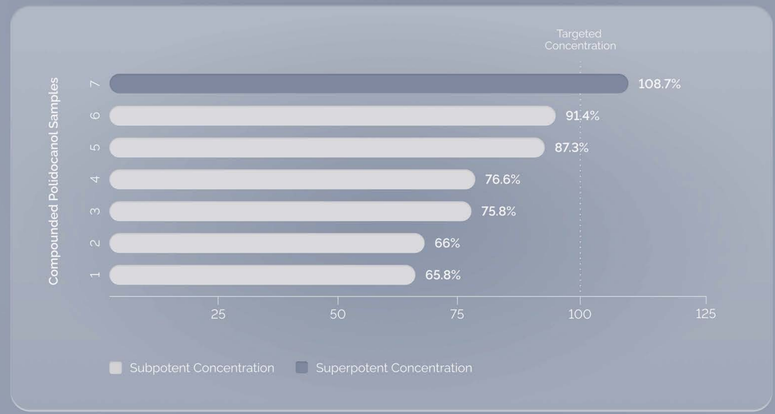
It's important to consider the consistency, quality, and efficacy of compounded solutions for your patients with varicose veins. Unlike FDA-approved Asclera, these formulations have not been evaluated for safety and efficacy and are not tested for stability, so potency or efficacy over time cannot be assured.[2] Compounded versions may even add preservatives that have not been studied for safety.

A November 2019 peer-reviewed study in the *Journal of Drugs in Dermatology (JDD)* found broad-ranging variations of actual polidocanol concentrations in 7 samples of compounded polidocanol.[3,†]

Compounding Impurity

As shown in study samples[3,‡]:

- **5 contained a 10-fold excess of impurities**
- **4 exceeded the limit of unknown impurities**
- **None were equivalent in potency and purity to Asclera**



Seven samples of polidocanol were obtained from 3 compounding pharmacies and analyzed using high pressure liquid chromatography.[‡]