ASCLERA®
(polidocanol) Injection

The Asclera® Difference

FDA-approved sclerotherapy treatment for uncomplicated spider and reticular veins in the lower extremities

Please see Important Safety Information throughout and Full Prescribing Information at Asclera.com

Trust the proven efficacy of Asclera®

Why Asclera®?

For more than 10 years, Asclera® has been FDA approved for the treatment of uncomplicated spider veins (≤ 1 mm in diameter) and reticular (small varicose) veins (1-3 mm in diameter) in the lower extremities.[1]

What were the results of the Asclera® clinical trial?

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

Study Design

Patients received one of the following (N = 338):

- 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

Methods

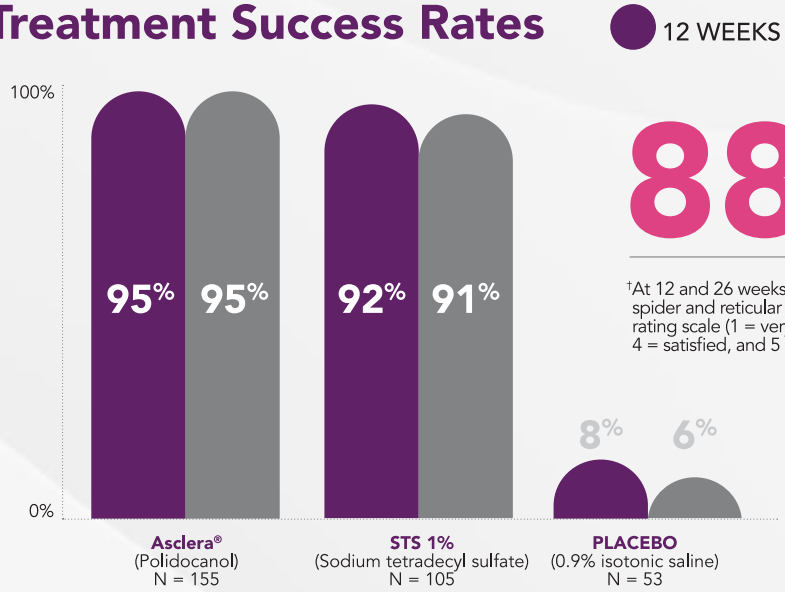
- Treatment 1: Intravenous injection of Asclera®, comparator, or placebo
- Treatments 2 and 3: If Treatment 1 was unsuccessful (defined as 1, 2, or 3 on a 5-point scale), additional treatments were given 3 and 6 weeks later
- Patients returned at 12 and 26 weeks after the last injection for final assessments

Treatment Success*

- Primary endpoint: improvement of veins judged by a blinded panel
- 95% of patients treated with Asclera® showed good or complete treatment success as rated by physicians
- Asclera® treatment results were statistically significant vs placebo ($p < 0.0001$) for the primary efficacy criterion "improvement of veins"

*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)

*Treatment Success Rates



88% of patients were satisfied or very satisfied with their Asclera® treatment at 12 weeks[2,†]

†At 12 and 26 weeks after last injection, patients were given digital images of their baseline spider and reticular (small varicose) veins and asked to rate their satisfaction using a verbal rating scale (1 = very unsatisfied, 2 = somewhat unsatisfied, 3 = slightly satisfied, 4 = satisfied, and 5 = very satisfied).

Asclera® (polidocanol) Injection Rx Only

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.

What outcomes are possible with Asclera® treatment?

Improvement 18 weeks after last treatment

Uncomplicated spider vein treatment (≤ 1 mm)
Patient treated with 0.5% Asclera®

Before | After

Uncomplicated reticular vein treatment (1-3 mm)
Patient treated with 1.0% Asclera®

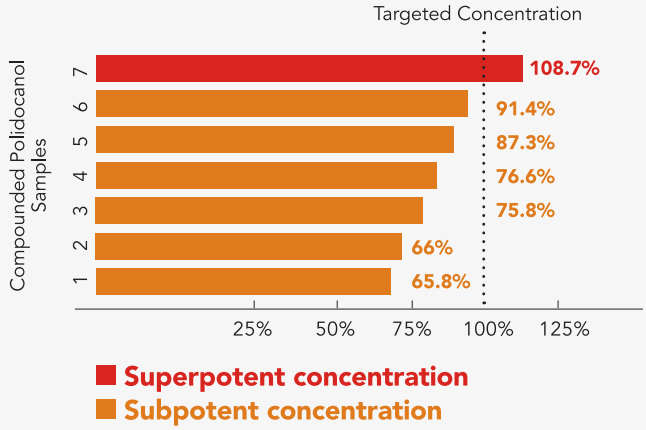
Before | After

Individual results may vary.

What about compounded polidocanol solutions?

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,‡]



Purity in compounding cannot be guaranteed

As shown in study samples[3,‡]:

- 5 contained a 10-fold excess of impurities
- 4 exceeded the limit for 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.

IMPORTANT SAFETY INFORMATION:
For intravenous use only.

CONTRAINDICATIONS:
Asclera is contraindicated for patients with known allergy to polidocanol and patients with acute thromboembolic diseases.

WARNINGS AND PRECAUTIONS:
Severe allergic reactions have been reported following polidocanol use, including anaphylactic reactions, some of them fatal.
Severe reactions are more frequent with use of larger volumes (> 3 mL). Minimize the dose of polidocanol.
Be prepared to treat anaphylaxis appropriately.

IMPORTANT SAFETY INFORMATION (Cont)

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 (within 3 months) major surgery, prolonged hospitalization or pregnancy are at increased risk for developing thrombosis.
Arterial Embolism: Stroke, transient ischemic attack, myocardial infarction, 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, urticaria generalized, 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, dermatitis allergic, 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 asclera.com

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.

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For more information please call 1-833-766-8346 (VEIN) .

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