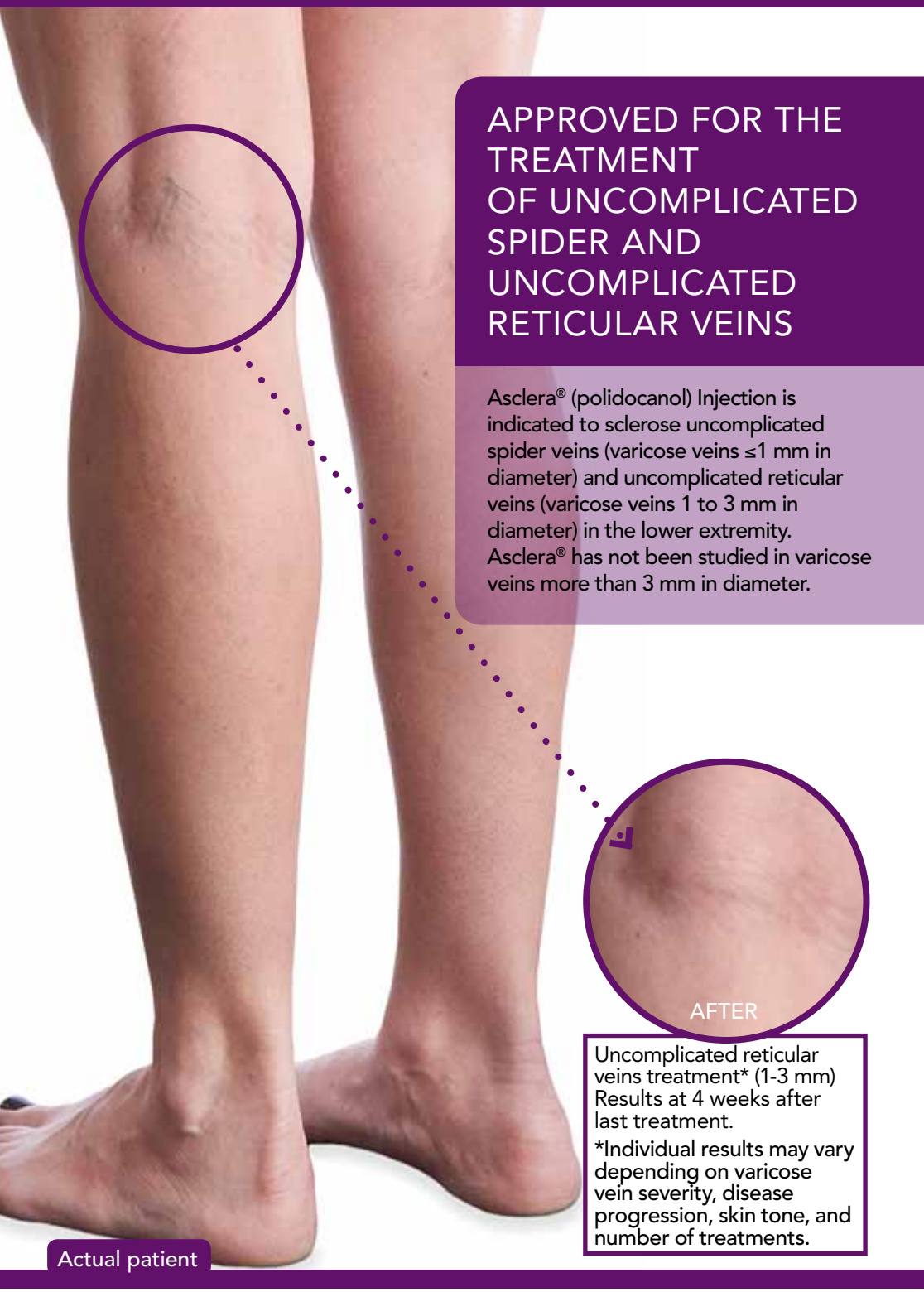
Asclera®
(polidocanol) Injection

APPROVED FOR THE TREATMENT OF UNCOMPLICATED SPIDER AND UNCOMPLICATED RETICULAR VEINS

Asclera® (polidocanol) Injection 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.



Actual patient

Uncomplicated reticular veins treatment* (1-3 mm) Results at 4 weeks after last treatment.

*Individual results may vary depending on varicose vein severity, disease progression, skin tone, and number of treatments.

IMPORTANT SAFETY INFORMATION:

For intravenous use only.

CONTRAINDICATIONS: Asclera® (polidocanol) Injection is contraindicated for patients with known allergy (anaphylaxis) to polidocanol and patients with acute thromboembolic diseases. **(Important Safety Information continued on next page)**

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CLINICAL RESULTS

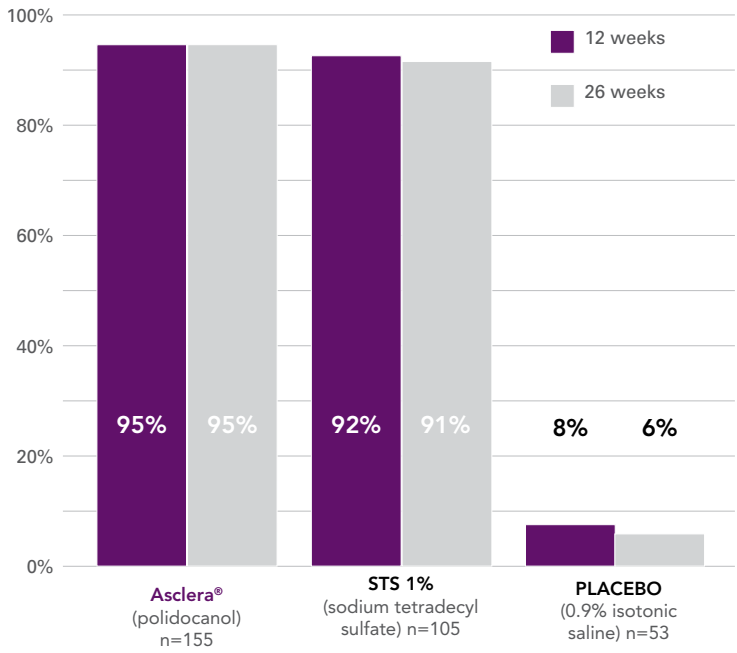
Asclera® was evaluated in a multicenter, randomized, double-blind, placebo and comparator-controlled trial (EASI-study) in patients with spider or reticular varicose veins. A total of 338 Caucasian patients, who were predominantly female, were treated with Asclera® [0.5% for spider veins (n=94), 1% for reticular veins (n=86), sodium tetradecyl sulfate (STS) 1% (n=105), or placebo (0.9% isotonic saline solution) (n=53)] for either spider or reticular veins. Patients received an intravenous injection in the first treatment session; repeat injections were given three and six weeks later if the previous injection was evaluated as unsuccessful (defined as 1, 2, or 3 on a 5-point scale).

Patients returned at 12 and 26 weeks after the last injection for final assessments. The primary effectiveness endpoint was improvement of veins judged by a blinded panel. Digital images of the selected treatment area were taken prior to injection, compared with those taken at 12 weeks post-treatment, and rated 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*

- 95% of patients treated with Asclera® showed good improvement or complete treatment success as rated by physicians
- Asclera® results were statistically significant when compared to placebo ($p<0.0001$) for the primary efficacy criterion "improvement of veins"

TREATMENT SUCCESS RATES



*Treatment success: Yes = Grade 4 to 5, No = Grade 1 to 3; derived from median of evaluation.

IMPORTANT SAFETY INFORMATION (Continued):

WARNINGS AND PRECAUTIONS:

Anaphylaxis: **Severe allergic reactions have been reported following polidocanol use, including anaphylactic reactions, some of them fatal. Severe reactions are most frequent with use of larger volumes (> 3 mL). The dose of polidocanol should therefore be minimized. Be prepared to treat anaphylaxis appropriately.**

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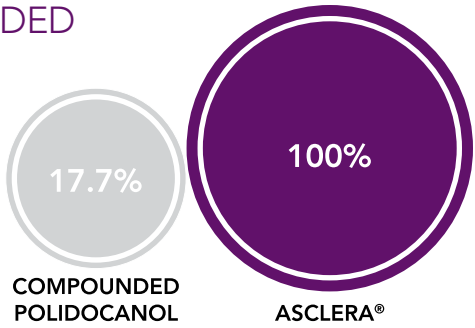
CONSISTENCY OF COMPOUNDED POLIDOCANOL SOLUTIONS*[1]

- Compounded polidocanol solutions did not deliver the claimed concentration five out of six times
- The GC/MS analysis showed impurities in all six compounded solutions

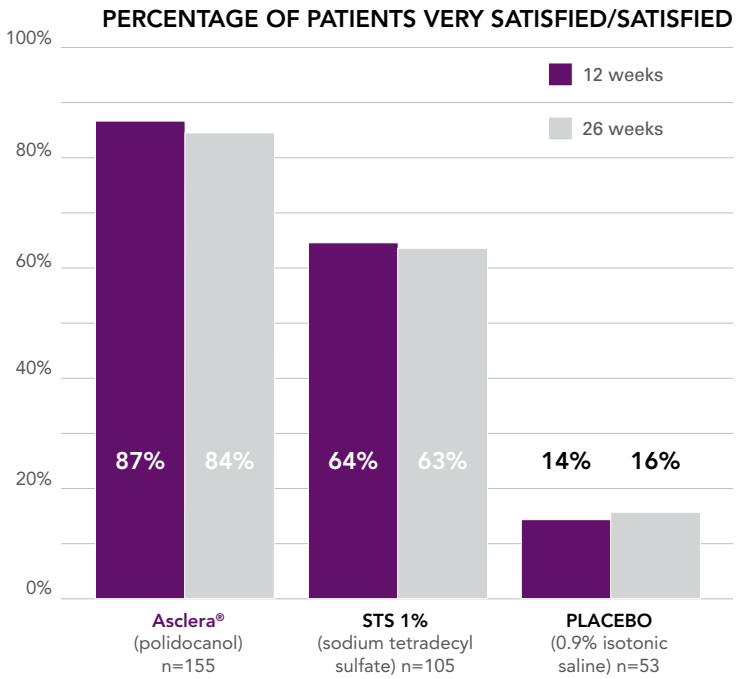


*Six samples of 1% polidocanol solutions obtained from four compounding pharmacies were evaluated using gas chromatography mass spectrometry (GC/MS) assays for POL concentrations and identification of material impurities.

PATIENT SATISFACTION*

In the EASI-study (referenced on previous page):

- 87% of patients were satisfied or very satisfied with their Asclera® treatment
- Patients were significantly more satisfied with Asclera® than with either STS or placebo ($p<0.0001$)



* At 12 and 26 weeks after last injection patients received the digital images of their treatment area taken at baseline and were asked to rate their satisfaction with their treatment using a verbal rating scale, where 1 = very unsatisfied, 2 = somewhat unsatisfied, 3 = slightly satisfied, 4 = satisfied, and 5 = very satisfied.

IMPORTANT SAFETY INFORMATION (Continued):

WARNINGS AND PRECAUTIONS (Continued):

Accidental Intra-arterial injection can cause severe necrosis, ischemia or gangrene. If this occurs, consult a vascular surgeon immediately.

Inadvertent Perivascular Injection of Asclera® can cause pain. If pain is severe, a local anesthetic (without adrenaline) may be injected.

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UNCOMPLICATED SPIDER VEINS TREATMENTS* (<1 MM)

Results at 4 weeks after last treatment

Results at 4 weeks after last treatment

Results at 26 weeks after last treatment

*Individual results may vary depending on varicose vein severity, disease progression, skin tone, and number of treatments.

IMPORTANT SAFETY INFORMATION (Continued):

WARNINGS AND PRECAUTIONS (Continued):

Severe adverse local effects, including tissue necrosis, may occur following extravasation; therefore, take care in intravenous needle placement and the smallest effective volume at each injection site should be used.

After the injection session is completed, apply compression with a stocking or bandage, and have the patient walk for 15-20 minutes. Keep the patient under supervision during this period to treat any anaphylactic or allergic reactions.

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.

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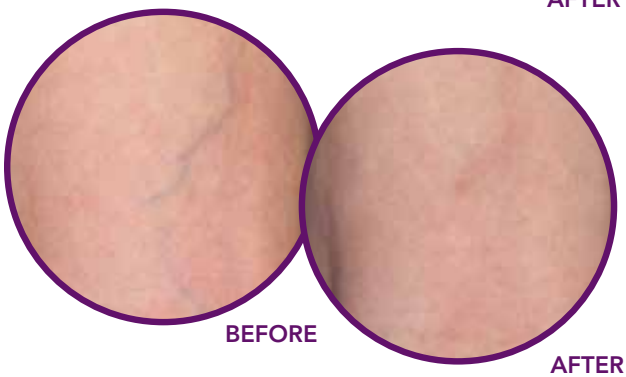
UNCOMPLICATED RETICULAR VEINS TREATMENTS* (1-3 MM)

Results at 4 weeks after last treatment

Results at 18 weeks after last treatment



Results at 26 weeks after last treatment

*Individual results may vary depending on varicose vein severity, disease progression, skin tone, and number of treatments.

ASCLERA® (POLIDOCANOL) INJECTION: A PROVEN TREATMENT FOR UNCOMPLICATED SPIDER AND UNCOMPLICATED RETICULAR VEINS

IMPORTANT SAFETY INFORMATION (Continued):

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

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ORDER ASCLERA® TODAY!

Call customer service at **866-862-1211**.

PROVEN STABILITY

- 3 year manufacturer shelf life
- Stable at room temperature
- Single dose ampule

ORDERING INFORMATION

DESCRIPTION	PART NUMBER	NDC
Asclera® (polidocanol) Injection 0.5%	7220121	46783-121-52
Asclera® (polidocanol) Injection 1%	7220221	46783-221-52

MERZ AESTHETICS™

[1]Weiss, Voigts, Howell (2011) Absence of Concentration Congruity in Six Compounded Polidocanol Samples Obtained for Leg Sclerotherapy. American Society for Dermatologic Surgery, Inc, Volume 37: 1-4.

EM00557-00

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