

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.tda.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.



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Welcome.





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.

Day Before Treatment

Purchase (20-30 mmHg)³ medium-grade compression stockings to wear after the procedure. This will support healing, reduce discomfort and swelling, and decrease risk of deep vein thrombosis.

Day Of Treatment

Avoid shaving or applying lotion to your legs and wear loose, comfortable clothing that allows access to the treatment area.

Before Treatment

During Treatment

After Treatment

Treatment typically lasts 15-45 minutes.



Antiseptic is used to clean the treatment area.



A very fine needle is used to inject Asclera.



A slight sting may accompany each injection.

At Home Instructions

Maintain compression day and night for 2 to 3 days after treatment for spider veins, and 5 to 7 days for reticular veins. Continue to maintain compression for 2-3 weeks during the daytime.

Walk 15-20 minutes immediately after treatment. Continue to take daily walks for the next 2-3 days.

For 2 to 3 days following treatment, avoid:



Heavy exercise



Long flights



Sunbathing



Hot baths or saunas

Common Side Effects

Common side effects typically last a few days to several weeks. Some side effects may take months or years to resolve. Common side effects include:

- Bruising and raised red areas
- Small skin sores
- Darkened skin in the form of lines or spots
- Multiple tiny red blood vessels

Risk Prevention

Inform your healthcare provider of all medicines, vitamins, and herbal products you're taking to ensure Asclera is suitable for you. If any of these conditions exist, do not receive Asclera treatment:

- Allergic to polidocanol
- · Acute vein or blood clotting (thromboembolic) disease
- Pregnant or nursing

Severe Reactions

Accidental Asclera injection near blood vessels can cause severe pain. If pain is severe, a local anesthetic (without adrenaline) may be injected.

Formation of small "burns" or ulcers can occur due to leakage of Asclera into the skin. These burns heal in time but may leave scarring.

In rare cases, potentially fatal anaphylactic reactions may occur. These reactions are most frequent with use of larger volumes (> 3 mL) of polidocanol.