

**Indication:**

Asclera® (polidocanol) Injection is a prescription medicine that is used in a procedure called sclerotherapy to remove unwanted veins on your legs. It is administered by a healthcare provider to treat two types of veins:

- Uncomplicated spider veins (very small varicose veins  $\leq$  1 mm in diameter)
- Uncomplicated small varicose veins (1 to 3 mm in diameter) known as reticular veins

Asclera® has not been studied in varicose veins more than 3 mm in diameter.

**IMPORTANT SAFETY INFORMATION FOR HEALTHCARE PROVIDERS:**

For intravenous use only.

**CONTRAINDICATIONS:** Asclera® (polidocanol) Injection is contraindicated for patients with known allergy (anaphylaxis) to polidocanol and patients with acute thromboembolic diseases.

**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.

**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.

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 reaction.

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 haematoma,

injection site irritation, injection site discoloration, injection site pain, injection site pruritus, injection site warmth, neovascularization, injection site thrombosis.