

June 17, 2010

Dear Health Care Professional:

The purpose of this letter is to provide you with safety information for **Asclera™ (polidocanol) Injection**, a new intravenous sclerotherapy treatment which has been approved by the U.S. Food and Drug Administration (FDA).

Asclera™ (polidocanol) Injection is a sclerosing agent indicated to treat uncomplicated spider veins (varicose veins ≤ 1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremities. Asclera™ (polidocanol) Injection has not been studied in larger varicose veins > 3 mm in diameter.

Important Safety Information

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

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.

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, should one occur.

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.

In clinical studies, the following adverse reactions were observed after using Asclera: injection site haematoma, injection site irritation, injection site discoloration, injection site pain, injection site pruritus, injection site warmth, revascularization, injection site thrombosis.

Reporting Adverse Events

Please read the accompanying FDA-approved full prescribing information for Asclera™ (polidocanol) Injection prior to administration for a complete understanding of the benefits and risks of Asclera™ (polidocanol) Injection in the treatment uncomplicated spider veins (varicose veins ≤ 1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremities. Asclera™ (polidocanol) Injection has not been studied in larger varicose veins > 3 mm in diameter.

Healthcare professionals should report any serious adverse events suspected to be associated with the use of Asclera™ (polidocanol) Injection to BioForm Medical at 1-866-868-1211. Alternatively, this information may be reported to FDA's MedWatch reporting system online (www.accessdata.fda.gov/scripts/medwatch), by phone (1 800-FDA-1088), by facsimile (1-800-FDA-0178), or mail using the MedWatch Form FDA 3500 (FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787).

Sincerely,



Brian K. Pilcher, PhD
Vice President, Medical Affairs and Clinical Education
BioForm Medical, Inc.