WIRB 20171347
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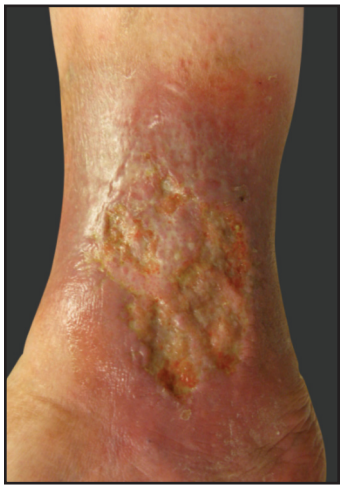
Now Enrolling Patients

Observational Study of the Effect of VarIthEna® on Wound Healing in the Treatment of Venous Leg Ulcers Resulting from Chronic Venous Insufficiency



Varithena® registry is now enrolling:

- Do you have a history of varicose veins and a venous leg ulcer (wound)?
- Have you had it for at least 3 months?

You might qualify for a clinical study and could be treated with Varithena®.

To find out more information, you can go to venouslegstudy.com or contact a local study physician at:

Sponsor: Provensis Ltd, A BTG International group company

BTG

INDICATIONS

Varithena® (polidocanol injectable foam) is indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein (GSV) system above and below the knee. Varithena® improves the symptoms of superficial venous incompetence and the appearance of visible varicosities.

IMPORTANT SAFETY INFORMATION

The use of Varithena® is contraindicated in patients with known allergy to polidocanol and those with acute thromboembolic disease.

Severe allergic reactions have been reported following administration of liquid polidocanol, including anaphylactic reactions, some of them fatal. Observe patients for at least 10 minutes following injection and be prepared to treat anaphylaxis appropriately.

Intra-arterial injection or extravasation of polidocanol can cause severe necrosis, ischemia or gangrene. Patients with underlying arterial disease may be at increased risk for tissue ischemia. If intra-arterial injection of polidocanol occurs, consult a vascular surgeon immediately.

Varithena® can cause venous thrombosis. 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.

The most common adverse events observed were pain/discomfort in extremity, retained coagulum, injection site hematoma or pain, common femoral vein thrombus extension, superficial thrombophlebitis, and deep vein thrombosis.

Physicians administering Varithena® must be experienced with venous procedures, possess a detailed working knowledge of the use of the duplex ultrasound in venous disease and be trained in the administration of Varithena®.

See Full Prescribing Information for Varithena®.

Varithena®
(polidocanol injectable foam) 1%