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Varithena® (polidocanol injectable foam) 1%
Media Fact Sheet

About Varithena®

Varithena® (polidocanol injectable foam) is the first and only FDA–approved foam for the treatment of incompetent great saphenous veins (GSV), accessory saphenous veins and visible varicosities of the GSV system above and below the knee. Varithena® improves the symptoms of superficial venous incompetence and the appearance of visible varicosities.[1]

Treatment with Varithena® is a minimally invasive, nonsurgical procedure for the treatment of varicose veins that only requires an ultrasound machine and standard medical supplies.[1]

Varithena® is a low-nitrogen (<0.8%), polidocanol foam dispensed from a proprietary canister device that provides patients and healthcare providers with an FDA-approved foam with established efficacy and safety; its proprietary method of preparation results in a cohesive foam with a uniform median bubble diameter of <100 µm, and no bubbles with a diameter >500 µm.[1] The distinctive gas mixture of oxygen:carbon dioxide in a ratio of 65:35 makes Varithena® the only standardized, low-nitrogen foam.

Although some physicians are currently compounding their own foams, no physician compounded foam is approved by the FDA. There are a number of variables in physician-compounded foams, such as type and concentration of the sclerosing agent, type of gas, ratio of liquid to gas, the time between processing and use, bubble sizes, and the method of preparation.

Varithena® sets a new standard for the treatment of both the symptoms and the appearance of varicose veins by providing physicians with the only FDA approved comprehensive therapy for the widest range of varicose veins— incompetent GSV, accessory saphenous veins and visible varicosities of the GSV system both above and below the knee.

Varithena® can be easily integrated into a vein-treatment specialist's practice. To facilitate integration, BTG offers both online and onsite instruction in administration and comprehensive reimbursement support.

Important Findings from VANISH-1 and VANISH-2 Clinical Trials

Efficacy

Varithena® has been studied in two pivotal placebo-controlled studies. VANISH-1 evaluated the safety and efficacy of a single treatment with Varithena® compared with placebo. VANISH-2 allowed for a second optional treatment 1 week later.[1]

Patients enrolled in VANISH-1 and VANISH-2 had saphenofemoral junction (SFJ) incompetence as evidenced by reflux of the great saphenous vein (GSV) or major accessory veins and experienced varicose vein symptoms. The mean baseline GSV diameter was 7.6 mm (range 1.5 to 25.9 mm) for patients treated in VANISH-1 and 8.7 mm (range 3.1 to 19.4 mm) for patients treated in VANISH-2.[1]

In both clinical trials, the primary efficacy endpoint was improvement in patient symptoms as measured by the change from baseline to week 8 in the VVSymQ® score.[1] The VVSymQ® score measures the burden of five patient-reported symptoms—heaviness, achiness, swelling, throbbing and itching (the HASTI™ symptoms). Symptoms were assessed daily using an electronic diary and averaged over 7 days.[1]

In both VANISH-1 and VANISH-2, treatment with Varithena® was statistically superior to placebo in improving symptoms as measured by change in VVSymQ® score.[1] Of patients who were treated with Varithena®, 64.7% of patients in VANISH-1 and 75.9% of patients in VANISH-2 had a clinically meaningful improvement in their symptoms at week 8 (i.e., the patient rated their symptoms as "moderately" or "much" improved compared to baseline).[1]

Significant improvements in appearance were also demonstrated with Varithena® compared with placebo, as reported both by patient self-assessment and by physicians in an independent review of photographs ($P<0.0001$ for both measures in VANISH-1 and VANISH-2).[1]

Other clinical-trial results from treatment with Varithena® included:

- Improvements in patient-reported quality of life as measured by VEINES-QOL;
- Improvements in the Venous Clinical Severity Score, as reported by clinicians
- Physiologic response rate of 80.4% in VANISH-1 and 86.2% in VANISH-2 defined as elimination of reflux through the SFJ and/or complete occlusion of all incompetent target trunk veins at baseline

Adverse Events

The safety profile of Varithena® was evaluated in 1,333 patients in 12 clinical trials, including three placebo-controlled, randomized trials.[1]

No clinically important neurologic or visual adverse events suggestive of cerebral gas embolism were seen in any of the 1,333 patients treated with Varithena®.[1] In the three placebo-controlled trials, the incidence of neurologic and visual adverse events within 1 day of treatment was 2.7% in patients treated with any dose of Varithena® (n=437) and 4.0% in placebo-treated patients (n=151).[1]

Patients should not be treated with Varithena® if they are allergic to polidocanol or have clots in their blood vessels.

Severe allergic reactions have been reported in people treated with liquid forms of polidocanol and some patients have died from these reactions. Varithena® is a foam made from polidocanol. A healthcare professional will observe the patient for signs of allergic reactions for at least 10 minutes after treatment with Varithena®.

Patients should tell their doctor about all of their medical conditions, including if they

- have arterial disease (a disease of the blood vessels)
- have reduced mobility
- have a history of blood clots in the veins or lungs
- have had major surgery in the past 3 months
- have recently had a long hospital stay
- are pregnant or have recently been pregnant

The most common side effects seen with Varithena® are leg pain or discomfort, injection site bruising or pain, and potentially serious blood clots in the leg veins. These are not all of the possible side effects of Varithena®. Patients should tell their healthcare provider about any side effect that bothers them or that does not go away. Patients can also report side effects to the FDA at 1-800-FDA-1088.

Varithena® is administered by a physician. Doctors using Varithena® must be experienced in vein procedures and trained in using Varithena®.

See Full Prescribing Information for Varithena®.

About VVSymQ®

The efficacy of Varithena® was evaluated using the VVSymQ® instrument, a patient-reported outcome (PRO) tool for the measurement of varicose vein symptoms.

VVSymQ® was developed and thoroughly tested by BTG for reliability, sensitivity, and content validity in accordance with FDA guidelines (2009) for the development of effective PRO instruments. It is the first and only varicose vein symptom PRO tool to meet these requirements.[7] (Note: VVSymQ® is not the only validated varicose vein symptom tool, but is the only tool validated to the standard of the FDA guidelines.)

Most treatment modalities have been evaluated using an ultrasound-based assessment to determine vascular patency/reflux. The FDA considers vascular patency/reflux to be a surrogate endpoint and not a direct measure of patient benefit.

VVSymQ® evaluates the burden of the five most relevant varicose vein symptoms (heaviness, achiness, swelling, throbbing, itching – the HASTI™ symptoms) using a scale of 0 (no symptoms) to 25 (all five symptoms experienced all the time). Symptoms were recorded using a daily electronic diary and averaged over 7 days to calculate the VVSymQ® score.[1]

About the Procedure

Treatment with Varithena® is a minimally invasive, nonsurgical procedure that only requires an ultrasound machine and standard medical supplies. There is no requirement for tumescent anesthesia or sedation.[1]

Varithena® is intended to act as follows: the foam displaces blood from the vein to be treated and scleroses the endothelium. [1]

Patients undergoing treatment with Varithena® can return to most normal activities and work following the procedure. Patients are encouraged to walk/mobilize the same day with minimal restrictions. The only restrictions post-treatment are to wear compression stockings for two weeks and to avoid heavy exercise for one week and extended periods of inactivity for one month.[1]

About Varicose Veins

Varicose veins are a clinical presentation of superficial venous insufficiency—a condition in which veins are inefficient in returning blood to the heart due to venous hypertension.[2,3] One-way valves that normally direct blood towards the heart are damaged or missing, and as a result, some blood refluxes (moves in the opposite direction) and often pools in the vein. [2, 3]

Varicose veins are 3 mm or greater in width,[4] appear twisted and cord-like, and tend to be blue to dark purple in color.[5,6]

Varicose veins are a real medical concern that often require treatment; patient-reported symptoms for varicose veins include heaviness, achiness, swelling, throbbing, and itching.[4]

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

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See Full Prescribing Information for Varithena®.

References

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