

FDA approved Asclera is used to treat spider and reticular leg veins

Know what to expect

Your sclerotherapy treatment with Asclera®



What to Expect from Treatment with FDA-approved Asclera®

What is Asclera?

Asclera (polidocanol) Injection is a prescription medication approved by the FDA for the treatment of uncomplicated spider veins (≤ 1 mm in diameter) and reticular (small varicose) veins (1-3 mm in diameter) in the lower extremities. It's used in a treatment called sclerotherapy, during which Asclera is injected into an affected vein, causing it to seal shut, eventually reabsorb into the body, and fade from view over time. The number of required treatments and outcomes of sclerotherapy vary from person to person, but typical treatment for spider and reticular (small varicose) veins is 1 to 3 injections. Sessions are usually spaced 1 to 2 weeks apart.

Is there any reason why I shouldn't receive Asclera treatment?

You shouldn't receive Asclera if you:¹

- Have a known allergy to polidocanol
- Have an acute vein or blood clotting (thromboembolic) disease
- Are pregnant or nursing

Be sure to tell your healthcare provider about all the medicines you are taking, including prescription and non-prescription medicines, vitamins and herbal products. Together, you can ensure that Asclera is right for you.

How can I prepare for treatment?

Before the day of your procedure:

- Purchase medium-grade compression stockings (20 to 30 mmHg)² to wear after the procedure to
 - Help maintain blood flow
 - Reduce discomfort and swelling
 - Support healing
 - Reduce risk of deep vein thrombosis

On the day of treatment:

- Avoid shaving your legs or applying lotion
- Wear loose comfortable clothing that allows access to the treatment area

What should I expect during the treatment?

- Each session typically lasts 15 to 45 minutes
- Antiseptic will be used to clean the treatment area
- A very fine needle will be used to inject Asclera into the treated veins
- A slight stinging may accompany each injection

Because every patient is different, each treatment and its results will vary. Factors include varicose vein severity, disease progression, skin tone, and extent of recommended treatments.

What do I need to do after treatment?

Please wear your compression stockings day and night for 2 to 3 days if treated for spider veins, 5 to 7 days if treated for reticular veins. Continue to wear them as needed for the following 2 to 3 weeks.

You should also walk 15-20 minutes immediately after treatment and daily for a few days.

What should I NOT do after treatment?

For 2 to 3 days following the treatment, avoid:

- Heavy exercise
- Sunbathing
- Long plane flights
- Hot baths, hot tubs, or saunas

Be sure to ask your healthcare provider if you are uncertain about any activities you should avoid post-procedure.

What potential changes are common after treatment?

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

These side effects usually go away within a few days to several weeks. Some side effects may take months or years to resolve.

What side effects require a call to my provider?

- An allergic reaction. 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) of solution
- In rare cases, formation of small “burns” or ulcers form, usually due to leakage of Asclera into the skin. These will heal in time but may leave a scar
- Inadvertent injection of Asclera around a blood vessel can cause pain. If pain is severe, a local anesthetic (without adrenaline) may be injected

Be sure to ask your provider about your individualized treatment plan with Asclera.

Please see Important Safety Information on the reverse

How well does Asclera® work?

In a clinical study, 88% of patients were satisfied or very satisfied with their Asclera treatment.*³

Ask your healthcare provider whether FDA-approved Asclera can help improve the appearance of your spider and small varicose veins. Visit www.asclera.com for more information.

WARNINGS AND PRECAUTIONS:

Arterial Embolism: Stroke, transient ischemic attack, myocardial infarction, 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 now been established and its use should be avoided.

Accidental injection into an artery can cause severe necrosis, ischemia or gangrene. Care should be taken in intravenous needle placement and the smallest effective volume at each injection site should be used. If intra-arterial injection of polidocanol occurs, consult a vascular surgeon immediately.

After the injection session is completed, apply compression with a stocking or bandage, and walk for 15-20 minutes. Your healthcare provider will provide monitoring during this period to treat any possible anaphylactic or allergic reactions. Maintain compression for 2 to 3 days after treatment of spider veins and for 5 to 7 days for reticular veins, or as directed by your Healthcare Provider. 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.

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.fda.gov/medwatch.

Please ask your healthcare provider or visit asclera.com for Full Prescribing Information.

REFERENCES

1. Asclera® Full Prescribing Information. Methapharm, Inc.
2. Weiss R, Weiss M, Beasley K. Sclerotherapy and vein treatment. McGraw Hill Medical, NY: 2012. ISBN: 978-0-07-14542-5.
3. 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.



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