



PATIENT : *Tamara*

AGE : 45

TREATMENT : *Asclera*

Actual patient

PATIENT 001

## My Story...

Due to my family history, I thought I was doomed to have unsightly veins. They appeared in the last five years and progressively got worse as the years went on. Since it's so common in my family, I thought I was just going to wear long pants for the rest of my life. When my dermatologist said that there was a treatment to help reduce the appearance of my varicose veins, I was surprised.

### 01 | What Bothered Me

Every day when I went out, I felt like I had to put on long pants. It didn't matter what I was doing. If I was in public, I was in long pants. It is an embarrassing thing to have to wear pants every day even when it's 90 degrees outside. I was seeing my dermatologist about another issue, and when he saw my spider veins, he told me about Asclera. At that point, I had never had any cosmetic procedures done before, and I wasn't aware of any treatments.

### 02 | My Treatment

This was my first cosmetic treatment. For the actual treatment, the needle used is very thin and goes right under the skin. The session took about 40 minutes. They taped cotton balls to each injection site and then put a bandage over the cotton balls, and I left the bandages on for the rest of the day.

### 03 | The Results

I have had one treatment done so far and now I don't feel like I have to wear long pants every day. I am scheduled for a second treatment because I had so many varicose veins, but I can already see a difference. It took six weeks for the results of the first treatment to show—not nearly as long as I have had to live with these veins. I went to a wedding this summer and, not only did I not wear long pants, I even went without nylons—it was so freeing. I feel like now I have other options in life.



# Addressing varicose veins

“If you look at a national survey, about 25 million Americans have spider veins. If you work out the math, that’s at least 1 in 10 Americans,” says Naperville, IL, dermatologist Jeffrey Hsu, MD.



## WHAT THE EXPERT SAYS

Asclera is an out-patient procedure because it is minimally invasive. Patients are typically comfortable and talking with me throughout the procedure. They are able to drive to and from the treatment by themselves.



BEFORE



AFTER

Individual results may vary.



## PATIENT TIPS

If you’re getting the treatment done for a special event, plan ahead. Also, try to schedule the procedure during cooler months so you’ll feel more comfortable in those compression stockings.

## What causes varicose veins

Whether the result of genetics, pregnancy, hormones or age, varicose and spider veins can cause your legs to look older. They are nothing more than enlarged veins that have been strained by increased pressure on the legs from prolonged standing and walking. In most cases they don’t cause any pain; but the look of them can be reason enough to do something about them.

## How to stop them

If you have a family history of leg veins, it’s best to avoid long periods of standing or sitting. You should also elevate your legs above heart level periodically, and avoid heavy lifting and putting unnecessary pressure on or crossing your legs. As an extra precaution, you can wear support hose to promote circulation. You may also want to limit your salt intake, as excess sodium can cause swelling in the lower extremities.

**ASCLERA**  
(polidocanol) Injection

Enjoy The Freedom to  
Show Your Legs

{ MORE > }

## 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 intravenous use only.

**CONTRAINDICATIONS:** Asclera® (polidocanol) Injection is contraindicated for patients with known allergy (anaphylaxis) to polidocanol and patients with acute vein and blood clotting 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. Please notify your healthcare provider if you have a known history of severe allergies or allergy to polidocanol.

**Accidental injection into an artery** can cause severe necrosis, ischemia or gangrene. If this occurs, consult your healthcare provider or a vascular surgeon immediately.

**Unintentional injection of Asclera outside of the vein** can cause pain. If pain is severe, a local anesthetic (without adrenaline) may be injected by your healthcare provider.

Severe adverse local effects, including tissue necrosis, may occur following flow of the product outside of the vein; therefore, 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 walk for 15-20 minutes. Your healthcare provider will provide monitoring during this period to treat any possible anaphylactic or allergic reactions.

**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 site pain, injection site itching, injection site warmth, neovascularization, injection site clotting.

You are encouraged to report any suspected adverse events. To report SUSPECTED ADVERSE REACTIONS, contact your Healthcare Provider, Merz Aesthetics at 1-866-862-1211, or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see a brief summary of prescribing information on page 149.



PATIENT 002

## My Story..

I first noticed my varicose veins in my late teens. They run in my family so it wasn't a surprise, but I saw them gradually increase and become more noticeable in my early 30s during pregnancy. At the time, I was also an engineer, working on my feet all day, which didn't help. After I had my two children, I decided to get treatment—I just didn't know that my varicose veins could be treated without surgery so finding out otherwise was great news.

PATIENT : *Milanka*

AGE : 38

TREATMENT : *Asclera*



### WHAT THE EXPERT SAYS

Weight gain, hormone fluctuations and lack of physical activity all contribute to varicose veins during pregnancy, but, according to Dr. Hsu, "The main theory right now is that it's not so much the pressure on the vascular circulation from weight but more so the hormone fluctuations dilating the veins that has a greater impact on the appearance of varicose veins."

### 01 | Initial Treatment

For the actual treatment they first cleaned the injection site. I was comfortably reclined in an exam chair, and my legs were injected in the front and the back. My treatment was completed in 20 minutes. The next day, I could still see discoloration, but I could also see a difference. It felt so good being proactive about something that had bothered me for years.

### 02 | The Follow Up

About three weeks after the initial treatment, I returned to have everything looked at and to have the varicose veins drained a little bit. They were a little sensitive, but I only noticed it when I rubbed up against something in the treated areas, and that felt like having a bruise. When the doctor drained them however, the sensitivity went away. Another three weeks after the follow up, I went back for another treatment. My legs were ready for another look. Due to the extensiveness of my varicose veins, Dr. Hsu recommended another treatment to enhance the results.

Actual patient



## Show off your legs...

“Asclera is medicine that we use in sclerotherapy to eliminate unwanted spider and varicose veins.” —Dr. Hsu



BEFORE



AFTER

Individual results may vary.

### 03 | The Results

I've been wearing shorts and everything else I used to avoid. It's a relief. It's really nice to be able to do that. Now, I honestly don't remember where some of my veins were on my legs. I had these veins for years.

### The process

Taking place over several weeks, the reaction caused by Asclera works over time. Basically, the injection causes the vein to gradually collapse. Once this happens, and the vein no longer transports blood, the body naturally dissolves it.

### Is it right for you?

Asclera is ideal for treating superficial varicose and spider veins. Even patients who have deep veins that need to be treated surgically could possibly benefit from Asclera as an adjunct procedure. “Many patients with deeper varicose veins suffer from surface spider veins as well,” Dr. Hsu says. “So after they have their deep veins treated surgically, they may be able to further enhance the results by treating surface veins with Asclera.”

**ASCLERA**  
(polidocanol) Injection

Enjoy The Freedom to  
Show Your Legs

### 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 intravenous use only.

**CONTRAINDICATIONS:** Asclera® (polidocanol) Injection is contraindicated for patients with known allergy (anaphylaxis) to polidocanol and patients with acute vein and blood clotting 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. Please notify your healthcare provider if you have a known history of severe allergies or allergy to polidocanol.

**Accidental injection into an artery** can cause severe necrosis, ischemia or gangrene. If this occurs, consult your healthcare provider or a vascular surgeon immediately.

**Unintentional injection of Asclera outside of the vein** can cause pain. If pain is severe, a local anesthetic (without adrenaline) may be injected by your healthcare provider.

Severe adverse local effects, including tissue necrosis, may occur following flow of the product outside of the vein; therefore, 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 walk for 15-20 minutes. Your healthcare provider will provide monitoring during this period to treat any possible anaphylactic or allergic reactions.

**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 site pain, injection site itching, injection site warmth, neovascularization, injection site clotting.

You are encouraged to report any suspected adverse events. To report SUSPECTED ADVERSE REACTIONS, contact your Healthcare Provider, Merz Aesthetics at 1-866-862-1211, or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see a brief summary of prescribing information on page 149.



# CONSUMER BRIEF SUMMARY

## Rx Only

## Asclera® (polidocanol) Injection

### IMPORTANT SAFETY INFORMATION ABOUT ASCLERA®

The brief summary does not take the place of talking to your healthcare provider about your medical condition or treatment.

### WHAT IS ASCLERA® (A SKLER AH)?

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 ≤ 1 mm in diameter)
- Uncomplicated small varicose veins (1 to 3 mm in diameter) known as reticular veins

### WHAT IS SCLEROTHERAPY?

Sclerotherapy is a minimally invasive procedure done by your healthcare provider to treat spider veins. The treatment involves the injection of a solution into the affected uncomplicated spider veins and uncomplicated reticular veins.

### HOW DOES ASCLERA® WORK?

Asclera® is a sclerosing agent that is injected into the vein. It works by damaging the endothelium, the cells lining the inside of blood vessels. This causes blood platelets to attach to the lining of the vessels; eventually, cellular debris and platelets cause the blood vessel to clot. Over time, the clotted vein will be replaced with tissue.

### HOW LONG IS EACH ASCLERA® SESSION?

A typical sclerotherapy session lasts 15 to 45 minutes. One injection is usually administered per inch with multiple injections per session.

### WHAT SHOULD I AVOID AFTER RECEIVING ASCLERA®?

For two to three days following the treatment, avoid (if you are uncertain, please ask your healthcare provider):

- Heavy exercise
- Long plane flights
- Sunbathing
- Hot baths or saunas

### YOU SHOULD TELL YOUR DOCTOR ABOUT ALL THE MEDICINES YOU ARE TAKING, INCLUDING:

- Prescription and nonprescription medicines, vitamins and herbal products.

### ARE THERE ANY POSSIBLE SIDE EFFECTS TO ASCLERA®?

#### YES, THEY MAY INCLUDE:

- 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.
- In rare cases formation of small "burns" or ulcers form usually due to leakage of Asclera® into the skin. They heal in time, but may leave a scar.
- 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 pruritus
- Injection site irritation
- Injection site warmth
- Injection site discoloration
- Neovascularisation
- Injection site pain
- Injection site thrombosis

### YOU SHOULD NOT BE TREATED WITH ASCLERA® IF YOU:

- Have a known allergy to polidocanol
- Have an acute thromboembolic disease
- Are pregnant or nursing

Review Important Safety Information with your healthcare provider. Asclera® is not recommended for use in children younger than 18 years of age.

### ADVERSE EVENTS

You are encouraged to report any adverse events suspected to be associated with the use of Asclera® (polidocanol) Injection to Merz Aesthetics at 1-866-868-1211. Alternatively, this information may be reported to FDA's MedWatch reporting system online ([www.accessdata.fda.gov/scripts/medwatch](http://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).

Distributed by: Merz Aesthetics, Inc.

## MERZ AESTHETICS™