

FDA approves first topical gel to ease redness of rosacea

August 27 2013



Mirvaso works by constricting dilated blood vessels of the face, company says.

(HealthDay)—Patients with the common skin condition rosacea can now turn to the first topical gel aimed at easing the redness that comes with the ailment.

The U.S. Food and Drug Administration on Monday approved Mirvaso (brimonidine) for the treatment of the redness—clinically known as erythema—that is a hallmark of rosacea. The gel is made by Galderma Laboratories, of Fort Worth, Texas, and was approved based on two month-long clinical trials involving more than 550 patients.

"Facial redness is the most common symptom of rosacea, but until now, physicians have been without prescription treatment options to specifically address this patient need," lead investigator Dr. Mark

Jackson, a dermatologist and clinical professor of medicine at the University of Louisville in Kentucky, said in a news release from Galderma.

"The FDA approval of Mirvaso marks a turning point in rosacea treatment: we are now able to provide patients that deal with the daily frustrations caused by the redness of rosacea with an [effective therapy](#)," he said.

One skin expert not connected to the company agreed.

"Up until this point, we have only had drugs to treat the bumps and pus pimples of rosacea," said Dr. Joshua Zeichner, director of cosmetic and clinical research in the department of dermatology at Mount Sinai Medical Center, in New York City. "The approval of Mirvaso is very exciting because for the first time, we have a medication to treat facial redness of rosacea, which previously could only be addressed with lasers. Facial redness is a significant issue for rosacea patients, so this drug will fill a large, unmet need."

Rosacea is a chronic inflammatory and vascular ailment that affects the face, causing redness and visible blood vessels as blemishes appear on the forehead, nose and cheeks. The condition is most common in people over 30 and is thought to affect about 16 million Americans, according to the news release.

The studies that led to Mirvaso's approval showed that the drug outperformed an inactive placebo gel in providing "significantly greater improvement in the facial redness of rosacea," the Galderma release said. Another trial, involving 276 patients, was conducted for a year.

According to the company, Mirvaso is thought to work by constricting otherwise dilated facial blood vessels, cutting down on the appearance of

redness. The gel is applied once a day to the forehead, chin, nose and cheeks, Galderma said. It will be available in pharmacies in September.

Another dermatologist cautioned that Mirvaso should not be seen as a cure for rosacea.

"This will not replace the need for other rosacea treatments for control of breakouts," said Dr. Doris Day, a dermatologist at Lenox Hill Hospital in New York City. However, she said, existing rosacea therapies "have been limited in their ability to treat or control redness."

Side effects from Mirvaso were rare. In the year-long study, less than 4 percent of the patients experienced reactions such as flushing, redness, burning sensations or headache, the company said. The gel is currently indicated for adults aged 18 or older, and should only be used "with caution" by people affected by depression or certain heart or autoimmune disorders.

More information: To find out more about rosacea, head to the [National Rosacea Society](#).

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Citation: FDA approves first topical gel to ease redness of rosacea (2013, August 27) retrieved 5 May 2024 from <https://medicalxpress.com/news/2013-08-fda-topical-gel-ease-redness.html>

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