



11960 Southwest 144th Street
Miami, Florida 33186
305-253-1916 ▼ Toll-Free: 888-253-5099
www.noven.com

PRESS RELEASE

MINIVELLE™ (ESTRADIOL TRANSDERMAL SYSTEM), THE SMALLEST ESTROGEN PATCH, NOW AVAILABLE IN U.S. PHARMACIES

Provides Effective Relief from Hot Flashes and Night Sweats Due to Menopause

Miami, FL and New York, NY, January 29, 2013 -- Noven Pharmaceuticals, Inc., the manufacturer of Vivelle-Dot® (estradiol transdermal system), today announced the availability of Minivelle™ (estradiol transdermal system) by prescription in U.S. pharmacies. On October 29, 2012, the U.S. Food and Drug Administration (FDA) approved Minivelle™ for the treatment of moderate to severe vasomotor symptoms due to menopause, commonly known as hot flashes and night sweats.

Minivelle™ is the smallest estrogen patch currently available. It is 34 percent smaller than Vivelle-Dot® and, at its lowest strength (0.0375 mg/day), has nearly the same surface area as a dime.

“Hot flashes and night sweats are the most commonly reported symptoms of menopause among women, said Mary Jane Minkin, M.D.,* clinical professor of obstetrics and gynecology at Yale University School of Medicine. “The availability of Minivelle™ in its unique size is significant as it offers women a discreet option to help manage these menopause symptoms.”

Minivelle™ is round with smooth, curved edges that may help prevent lifting or snagging associated with everyday wear. It leaves almost no sticky residue and causes almost no skin irritation. During clinical pharmacology studies with Minivelle™, 35 percent or less of subjects experienced barely perceptible erythema. Minivelle™ stays in place during showering and exercising and 100 percent of the subjects reported that their patch stayed on completely over the wear period.

“The launch of Minivelle™ is an example of our commitment to providing innovative products tailored to women’s active and busy lifestyles, and adds to our growing portfolio – established more than 16 years ago – of treatment options for menopausal women,” said Jeffrey F. Eisenberg, Noven’s President and Chief Executive Officer.

As a part of its commitment, Noven offers a savings program to help reduce Minivelle™ co-pays for eligible patients. On co-pays up to \$70, patients pay no more than \$15 for a one-month supply. On co-pays in excess of \$70, patients may qualify for up to \$55 in savings for a one-month supply. Patients can take advantage of this offer each month, for up to 12 uses. Restrictions apply. Physicians and patients should review the full terms and conditions at www.minivelle.com.

“I’m excited to talk to my doctor about Minivelle™, which is from the manufacturer of the patch I’ve known and trusted to help relieve my menopausal hot flashes and night sweats,” said Karen Giblin,* founder of Red Hot Mamas, a menopause education and support program. “I never want to feel like menopause defines me, and the small size of Minivelle™ is appealing as it can help alleviate my symptoms, yet no one has to know I’m wearing it.”

About Minivelle™

Minivelle™ is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause, commonly known as night sweats and hot flashes. At 2.48 cm², the patch, at its lowest strength (0.0375 mg/day), has nearly the same surface area as a dime, making it the smallest estrogen therapy patch currently available. Minivelle™ has been approved with four dosing options – 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day and 0.1 mg/day. Minivelle™ is manufactured by Noven Pharmaceuticals, Inc. (the manufacturer of Vivelle-Dot®), and is marketed and sold through the Women’s Health unit of Noven’s subsidiary, Noven Therapeutics, LLC.

Minivelle™ contains bioidentical estradiol, a plant-based estrogen that is chemically identical to the estrogen produced naturally by a woman’s body. This does not mean there are differences in safety or efficacy compared to other estrogen therapies. Minivelle™ is designed to release estradiol continuously upon application, increasing estradiol levels above baseline within four hours, and, with its DOT Matrix™ technology, allows for efficient delivery of estradiol.

Minivelle™ is bioequivalent to Vivelle® (estradiol transdermal system), with the same demonstrated safety and efficacy for the treatment of moderate to severe vasomotor symptoms due to menopause, commonly known as hot flashes and night sweats. No clinical trials were conducted with Minivelle™. The most commonly reported adverse events for Vivelle® (≥5 percent) were headache, breast tenderness, back and limb pain, common cold, upset stomach, nausea, inflammation of the sinuses, and irregular vaginal bleeding or spotting.

For more information, including the full Prescribing Information, visit www.minivelle.com and read the Important Safety Information below.

INDICATION

MINIVELLE™ (estradiol transdermal system) is a prescription medicine patch that contains estradiol (an estrogen hormone). MINIVELLE is used to treat moderate to severe hot flashes due to menopause.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about MINIVELLE (an estrogen hormone)?

- **Using estrogen-alone may increase your chance of getting cancer of the uterus (womb). Report any unusual vaginal bleeding right away while you are using MINIVELLE. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus**

(womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause

- **Do not use estrogen-alone to prevent heart disease, heart attacks, strokes, or dementia (decline in brain function)**
- **Using estrogen-alone may increase your chances of getting strokes or blood clots**
- **Using estrogen-alone may increase your chance of getting dementia, based on a study of women 65 years of age or older**
- **Do not use estrogens with progestins to prevent heart disease, heart attacks, strokes, or dementia**
- **Using estrogens with progestins may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots**
- **Using estrogens with progestins may increase your chance of getting dementia, based on a study of women 65 years of age or older**
- **You and your healthcare provider should talk regularly about whether you still need treatment with MINIVELLE**

MINIVELLE should not be used if you have unusual vaginal bleeding, currently have or have had certain cancers, had a stroke or heart attack, currently have or have had blood clots, currently have or have had liver problems, have been diagnosed with a bleeding disorder, are allergic to MINIVELLE or any of its ingredients, or think you may be pregnant.

The most common side effects that may occur with MINIVELLE are headache, breast tenderness, back and limb pain, common cold, upset stomach, nausea, inflammation of the sinuses and irregular vaginal bleeding or spotting.

MINIVELLE should be used at the lowest effective dose and for the shortest duration consistent with your treatment goals and risks.

About Menopause

Menopause is a natural part of every woman's life. The average age of a woman entering menopause is 51 years old. Menopause is typically confirmed when a woman has missed her menstrual periods for 12 consecutive months. During perimenopause, the transition period before a woman reaches menopause, estrogen levels gradually decline and periods may become irregular. The severity of symptoms associated with going through menopause varies from woman to woman. Hot flashes are the most common symptom of menopause. Because the journey is unique for each woman, it is important for women going through menopause to have a thorough discussion about the transition with their doctors and determine if treatment is appropriate.

About Noven

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven is committed to developing and offering products and technologies that meaningfully benefit patients, its customers and its industry partners. Noven is a stand-alone operating subsidiary of Japan-based Hisamitsu Pharmaceutical Co., Inc., and serves as Hisamitsu's U.S. growth platform

in prescription pharmaceuticals. For more information about Noven, visit www.noven.com. For information about Hisamitsu, visit www.hisamitsu.co.jp/english.

*Mary Jane Minkin, M.D. and Karen Giblin are paid consultants for Noven Pharmaceuticals, Inc.

All opinions stated are those of the individual.

#

Contacts

Joseph C. Jones
Vice President – Corporate Affairs
Noven Pharmaceuticals, Inc.
305-253-1916

Samantha Schwarz
Executive Director
GolinHarris
312-729-4370