

**P R E S S   R E L E A S E**

**New Minivelle® (Estradiol Transdermal System) 0.025 mg/day Dose Now Available by Prescription in U.S. Pharmacies**

*New dose approved by FDA for the prevention of postmenopausal osteoporosis only; higher doses of Minivelle can also treat moderate to severe hot flashes due to menopause*

**MIAMI and NEW YORK, February 12, 2015** -- Noven Pharmaceuticals, Inc. today announced that the new 0.025 mg/day dosage strength for Minivelle® (estradiol transdermal system) is now available by prescription nationwide for only the prevention of postmenopausal osteoporosis. The FDA initially approved Minivelle in October 2012 to treat moderate to severe vasomotor symptoms (VMS) due to menopause, commonly known as hot flashes. In September 2014, the FDA approved a new indication for prevention of postmenopausal osteoporosis for all doses of Minivelle. The new 0.025 mg/day low dose was approved for this indication only.

The new 0.025 mg/day patch is 33% smaller than Minivelle 0.0375 mg/day, already about the size of a dime, making the 0.025 mg/day patch the world's smallest estrogen therapy patch ever. Minivelle is now available with five dosing options – 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day, with the newly available lower dose of 0.025 mg/day indicated for the prevention of postmenopausal osteoporosis only. The higher doses are indicated to treat moderate to severe VMS as well. If a patient uses Minivelle only to prevent osteoporosis from menopause, they should talk with their healthcare provider about whether a different treatment or medicine without estrogens might be better for them.

“The journey of menopause is unique for each woman, and this additional indication and new dosage strength of Minivelle – for the prevention of osteoporosis only – allow women and their doctors to individualize treatment to best fit each woman's needs,” said Joel Lippman, MD, FACOG, Noven's Executive Vice President – Product Development and Chief Medical Officer. “As the world's smallest estrogen therapy patch, Minivelle is an example of an innovative product tailored to women's active and busy lifestyles.”

Noven offers a savings program to help reduce the Minivelle co-pay for eligible patients. Eligible patients may pay as little as \$15 each month for up to 12 uses on their Minivelle prescriptions. Restrictions may apply. For more information, including full terms and conditions, visit [www.MINIVELLE.com](http://www.MINIVELLE.com).

**About Minivelle®**

Minivelle is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause, commonly known as hot flashes, and the prevention of postmenopausal osteoporosis. If a patient uses Minivelle only to prevent osteoporosis from menopause, they

should talk with their healthcare provider about whether a different treatment or medicine without estrogens might be better for them.

Minivelle is bioequivalent to Vivelle® (estradiol transdermal system), which demonstrated safety and efficacy for the treatment of moderate to severe vasomotor symptoms due to menopause, commonly known as hot flashes. Efficacy and safety of Vivelle in the prevention of postmenopausal osteoporosis have been demonstrated in a 2-year double-blind, randomized, placebo-controlled, parallel group study. 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.

Minivelle contains bioidentical estradiol, a plant-based estrogen that is chemically identical to the estrogen produced naturally by a woman's body. Noven's transdermal drug-delivery of estrogens by Minivelle allows for efficient delivery of estradiol through the skin, bypassing first-pass metabolism. The clinical significance of this has not been established and this does not mean that Minivelle is safer or more effective than other hormone therapies.

Minivelle is round with smooth, curved edges that may help prevent lifting or snagging associated with everyday wear and stays in place during showering and exercising. 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.

At 1.65 cm<sup>2</sup>, the new 0.025 mg/day patch is 33% smaller than Minivelle 0.0375 mg/day that is already only about the size of a dime. Minivelle is now approved with five dosing options – 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day with the newly approved, lower dose of 0.025 mg/day indicated for the prevention of postmenopausal osteoporosis only.

Please read the Important Safety Information below and for more information, including the full Prescribing Information, visit [www.MINIVELLE.com](http://www.MINIVELLE.com).

## **INDICATION**

MINIVELLE® (estradiol transdermal system) is a prescription medicine patch that contains estradiol (an estrogen hormone). MINIVELLE is used to reduce moderate to severe hot flashes due to menopause and to help prevent postmenopausal osteoporosis (thin weak bones).

If you use MINIVELLE only to prevent osteoporosis from menopause, talk with your healthcare provider about whether a different treatment or medicine without estrogens might be better for you.

## 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 as vaginal bleeding after menopause may be a warning sign of cancer of the uterus. Your healthcare provider should check any unusual vaginal bleeding to find out the cause.**
- **Do not use estrogen-alone or estrogen with progestins 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, while using estrogens with progestins may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots.**
- **Using estrogen-alone or estrogen 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.

Before you take MINIVELLE, tell your healthcare provider if you have unusual vaginal bleeding, have any other medical conditions, are going to have surgery or will be on bed rest, are breast feeding, and about all of the medicines you take.

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.

These are not all the possible side effects of MINIVELLE. Please read the Patient Information section within the full Prescribing Information before taking MINIVELLE. For more information ask your healthcare provider or pharmacist for advice about side effects.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

## **About Noven**

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven's mission is to develop and offer pharmaceutical products that meaningfully benefit patients around the world, with a commitment to advancing patient care through transdermal drug delivery. 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](http://www.noven.com). For information about Hisamitsu, visit [www.hisamitsu.co.jp/english](http://www.hisamitsu.co.jp/english).

Minivelle® is a registered trademark of Noven Therapeutics, LLC.

Vivelle® is a registered trademark of Novartis AG.

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