



Divigel<sup>®</sup>

(estradiol gel) 0.1%

0.25 mg 0.5 mg 1 mg

# *Hot Flashes & Night Sweats*

See inside for information on menopause,  
hot flashes, and night sweats and how  
Divigel<sup>®</sup> (estradiol gel) 0.1% can help you

[www.divigel.com](http://www.divigel.com)

# Understanding Hot Flashes & Night Sweats

- ❑ **Are you suffering from uncomfortable hot flashes and night sweats that cause a sudden feeling of intense warmth in your face and chest...**
- ❑ **followed by skin redness (flushing), heavy sweating...**
- ❑ **and finally often a cold, clammy feeling?**
- ❑ **Are “night sweats” (or hot flashes at night) interrupting your sleep?**

## You Are Not Alone

Up to 85% of women suffer from symptoms such as hot flashes or night sweats (hot flashes that may disrupt sleep).<sup>1</sup> Hot flashes and night sweats usually last for 3 to 5 years before they taper off. Some women may never have a hot flash or night sweat and some may have them for many years.<sup>2</sup>



## What Are Hot Flashes & Night Sweats?

- 💧 Hot flashes and night sweats can be uncomfortable and embarrassing
- 💧 Hot flashes and night sweats begin as a feeling of intense warmth in the upper body. They usually begin in the head and spread down into the neck and chest<sup>3-4</sup>
- 💧 The skin turns red (flushing).<sup>2</sup> This is followed by heavy sweating, and finally often a cold, clammy feeling<sup>3</sup>
- 💧 Some women may also have fast heartbeats (palpitations)<sup>2</sup>
- 💧 Hot flashes and night sweats usually last from 1 to 5 minutes<sup>3,5</sup>
- 💧 Hot flashes during the night (“night sweats”) may wake up women and make it difficult to get enough sleep. Frequent sleep interruptions can cause tiredness and irritability the next day<sup>2</sup>

Hot flashes and night sweats are just some of the many symptoms of menopause.

## Menopause: The “Change of Life”

Menopause is commonly referred to as the “change of life”. Until menopause, the ovaries make most of the body’s estrogen. As a woman gets older, her ovaries gradually stop producing estrogen. This usually starts when women are in their mid-to-late 40s. When the estrogen levels fall low enough, menstrual periods stop.<sup>2,4</sup> The final menstrual period usually happens when women are about 50 or 51 years old. A woman knows for sure when she has not had a menstrual period for 12 months in a row. After menopause, ovulation stops and the woman can no longer become pregnant.<sup>3</sup>

Menopause may also occur if the ovaries have been surgically removed, or damaged by radiation or chemotherapy.<sup>3-4</sup>

When a woman gets close to entering menopause, she may begin to notice hot flashes and night sweats with other changes in her body.<sup>3-4</sup>

When estrogen levels fall, this can cause or worsen symptoms such as hot flashes and night sweats that may interrupt sleep.<sup>1</sup>

💧 The drop in estrogen levels is thought to affect an area of the brain that controls body temperature<sup>2</sup>

💧 In a hot flash or night sweat, the brain mistakenly senses that the body is too hot even though it is not. This area of the brain signals the body to release excess heat. One way the body does this is by widening the blood vessels, especially those near the skin of the head, face, neck, and chest. This brings more blood closer to the surface of the skin and causes the skin to look flushed or red. A woman may also sweat to cool the body further<sup>2</sup>

💧 After a short time, when the body has released the excess heat, the person could feel cold and clammy<sup>2-3</sup>

## Symptoms

The symptoms of menopause are different for every woman. Some women may have troublesome symptoms and others may have no symptoms at all.<sup>1</sup> Symptoms may depend on family history, age of onset of menopause, smoking, diet, number of births, body-mass index (BMI), exercise as well as ethnic origin<sup>3</sup>

## Complaints from women around menopause include:<sup>1,3,6</sup>

- Hot flashes
- Night sweats
- Sleep problems
- Vaginal dryness
- Bladder problems
- Severe tiredness
- Mood swings
- Body aches

Most of the symptoms disappear within a few months for many women but sometimes they can persist for several years after the last menstrual period.<sup>3</sup>

As a woman ages after menopause, there is a natural increased risk of developing other health conditions. This includes an increased risk of heart disease, drying of the skin, and lack of interest in sex. Low estrogen after menopause can also speed up bone loss and increase a woman's risk of developing osteoporosis ("brittle bones").<sup>1,2,3</sup>

Please note there are various products indicated for specific symptoms associated with menopause. Divigel® is indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause.<sup>4</sup>



## Lead a Healthy Lifestyle<sup>2</sup>

The first approach to reducing symptoms of menopause is to lead a healthy lifestyle. These simple lifestyle changes may help manage your hot flash and night sweat symptoms.

- 💧 **Try to find out what causes your hot flashes and night sweats so that you can avoid them.** You may find that hot drinks, hot or spicy foods, alcohol, caffeine, cigarette smoking, stress, hot weather or a warm room may trigger a hot flash or night sweat
- 💧 **Stay cool** during the day and night with a fan or air conditioner
- 💧 **Dress in layers** so that you can easily remove clothing to cool down
- 💧 **Use layered bedding** to help you stay cool in case you have “night sweats”
- 💧 **Keep cool water at your bedside** to sip if you awaken during sleep
- 💧 **Learn to control your breathing during a hot flash or night sweat.** Practice taking slow, deep, rhythmic breaths
- 💧 **Exercise regularly.** This will help reduce stress and help you get a better night’s sleep but don’t exercise too close to bedtime (this may induce night sweats)



## Questions to Ask Your Healthcare Provider

Along with these lifestyle changes, some women may choose estrogen therapy. Before starting estrogen therapy, be sure to discuss these questions with your healthcare provider:

- What treatment options are available to treat my symptoms?
- What are the benefits and risks of estrogen therapy that I need to know?
- Who should not take estrogen?
- What side effects might I experience?
- How long will I have to use estrogen?

Medications will help reduce some of the symptoms of menopause. However, they all have some risks. Please speak with your healthcare provider about estrogen therapy and find out if it is right for you.<sup>4</sup>

*All medicines containing estrogen used to treat hot flashes and night sweats should be used at the lowest dose possible for your treatment and only as long as needed.<sup>2</sup>*



## How Does Divigel® (estradiol gel) 0.1% Treat Hot Flashes & Night Sweats?

*Divigel® has been designed to help reduce the frequency and severity of hot flashes, including night sweats.*

- Divigel® is approved by the Food and Drug Administration as safe and effective for the treatment of moderate to severe vasomotor symptoms (hot flashes, including night sweats) associated with menopause. Divigel® has been proven to reduce the severity and frequency of vasomotor symptoms<sup>4</sup>
- Divigel® contains estradiol—an FDA-approved synthetic estrogen that is derived from a plant source.<sup>4</sup> Estradiol is bioidentical estrogen—this means that it is identical to estrogen produced by women's ovaries.<sup>4</sup> Estrogen is considered to be the most effective medication available to relieve hot flashes and night sweats<sup>1</sup>
- Divigel® is a gel that is applied to the skin. It contains the lowest dose of estradiol compared to any other approved estrogen gels or lotions available to treat hot flashes, including night sweats.<sup>4,7-11</sup> Divigel® requires a small amount of gel applied to a small area of skin on the upper thigh, about the size of a 5" x 7" photograph<sup>4</sup>
- An advantage of Divigel® is that you can take a lower dose of estradiol than if you took estrogen by mouth. This is because Divigel® is quickly absorbed through the skin and goes directly into the bloodstream.<sup>4</sup> Estrogen taken by mouth must be given in large doses because it first has to pass through the stomach, intestines, and liver before reaching the bloodstream
- Divigel® is easy to use and only has to be applied once a day<sup>4</sup>

Divigel® is available in 3 different dosages so your healthcare provider can tailor treatment for you<sup>4</sup>

- 0.25 mg estradiol
- 0.5 mg estradiol
- 1 mg estradiol

Your healthcare provider may prescribe the lowest possible dose of Divigel® for the shortest time needed. Please read the Divigel® Patient Information leaflet that comes with the medicine as well as the Important Safety Information on pages 15 and 16 that discusses the risks of using estrogens and when estrogen products should not be used.<sup>4</sup> For additional information, refer to [www.divigel.com](http://www.divigel.com) for Full Prescribing Information.

Once you begin using Divigel®, talk to your healthcare provider every 3 to 6 months about whether treatment is still needed. Your healthcare provider can decide if you need to adjust your dose based upon your response.

### Getting Started on Divigel®

Divigel® has been proven to reduce the severity and frequency of vasomotor symptoms.<sup>4</sup> It is very important that you take time before starting the medicine so that you can:

- Read the patient education leaflet
- Learn how to apply Divigel® and manage your treatment
- Plan a daily schedule
- Plan time to keep your healthcare provider's appointments as well as get your prescription refills so that you do not miss any doses

This will help you get the most benefit from Divigel®. You must use Divigel® correctly in order for the medicine to help relieve hot flashes and night sweats.

## Learn How Easy It Is to Use Divigel®<sup>4</sup>

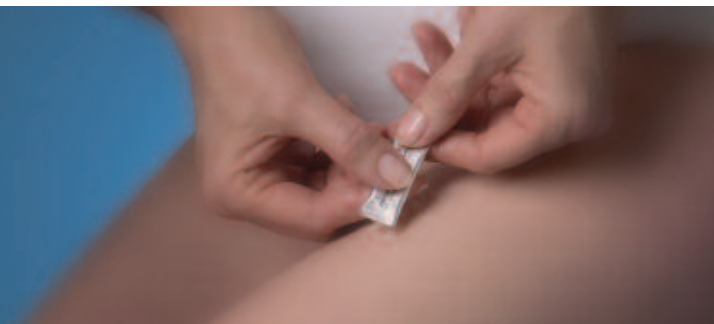
*Divigel® is a clear, smooth gel that is odorless and invisible when dry. Only you will know that you are using it.*<sup>4</sup>

### Before Use

- 💧 Wash and dry your hands thoroughly
- 💧 Make sure the application area is clean and dry

### How to Apply Divigel®

- 💧 Apply Divigel® at about the same time each day
- 💧 Sit in a comfortable position
- 💧 Cut or tear open a Divigel® packet
- 💧 Apply Divigel® to clean, dry, and unbroken skin (without cuts or scrapes). If you take a bath or shower, be sure to apply your Divigel® after your skin is dry
- 💧 Use your thumb and index finger to squeeze the entire contents of the Divigel® packet on the skin of the upper thigh



- 💧 Apply Divigel® to the left upper thigh one day and the right upper thigh the next day. This will help prevent skin irritation

- 💧 Spread the gel on the upper thigh over an area about the size of a **5" x 7" photograph**. You do not need to massage or rub in Divigel®



- 💧 Keep Divigel® away from your face, eyes, and breasts or in or around the vagina
- 💧 **Do not smoke while handling or applying Divigel® packets**
- 💧 Store Divigel® at room temperature. Keep Divigel® away from heat or flames until the gel has dried

### After Use

- 💧 Throw the empty Divigel® packet in the trash. Keep out of the reach of children and pets
- 💧 Wash your hands with soap and water immediately after applying Divigel®. This will remove any gel left on your hands to help prevent spreading the medicine from your hands to other people
- 💧 Do not allow the site to get wet for 1 hour after Divigel® is applied
- 💧 Allow the gel to dry completely before dressing. Divigel® is a quick-drying gel, so there is little time to wait before dressing and no sticky residue is left behind

## Action Steps

You will get the most relief from your hot flashes and night sweats if you are willing to take these three Action Steps:

### □ Action Step #1: Use Divigel® every day at the same time.

Divigel® is a once-daily topical gel. It should be applied every day around the same time to work at its best.<sup>2</sup> Make Divigel® a part of your daily routine to help you remember to apply it each day.

### □ Action Step #2: Be patient and give Divigel® time to reduce your hot flashes.

It may take up to 2-7 weeks before you see the most significant relief of your hot flashes with Divigel®.<sup>12</sup> So...stay with your therapy!

### □ Action Step #3: Refill prescriptions on time and keep all appointments with your healthcare provider.

It is important to apply Divigel® every day.<sup>2</sup> Be sure that you do not run out of Divigel®. This is why you must get your refills on time.

Estrogen should be used at the lowest dose for the shortest amount of time needed to control your hot flashes and night sweats.<sup>2</sup> Plan to keep all your appointments with your healthcare provider (about every 3 to 6 months) to make sure that you are taking the right dose only as long as you need it. Please refer to the accompanying Divigel® Patient Information leaflet. It is important to understand when to contact your healthcare provider with questions or concerns.

## What should I do if I miss a dose?<sup>4</sup>

If you miss a dose of Divigel® it is important to determine how many hours have passed since you should have taken your dose.

Use this chart to decide what to do if you forget to apply a dose of Divigel®.

### How Many Hours Have Passed Since You Missed Your Dose?

If you remember **within 12 hours** of your normal dose



APPLY THE MISSED DOSE NOW. Resume your normal schedule on the next day.

If you remember **more than 12 hours** after your normal dose



SKIP THE MISSED DOSE. Resume your normal schedule on the next day.

💧 **Do not apply Divigel® more than once each day**

💧 **If you miss a dose, do not double the dose on the next day to catch up**



## Be Patient

It may take 2 to 7 weeks before Divigel® starts to relieve your hot flashes.<sup>12</sup> Be sure to keep all your appointments with your healthcare providers to discuss your progress and answer any questions you might have. Talk with your healthcare provider before you change your dose or stop using Divigel®.

*Divigel® comes with a Patient Information leaflet. Please read it and follow the directions carefully. This leaflet contains important information about your treatment as well as guidance about when it is important to contact your healthcare provider.*



## Important Safety Information for Patients

**The following are not all the possible risks for Divigel®.**

- Estrogens increase the chance of getting cancer of the uterus. Report any unusual vaginal bleeding right away while you are taking estrogens. 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. In general, the addition of a progestin is recommended for women with a uterus to reduce the chance of getting cancer of the uterus
- Do not use estrogens, with or without progestins, to prevent heart disease, heart attacks, or strokes. Using estrogens, with or without progestins, may increase your chance of getting heart attacks, strokes, breast cancer, and blood clots
- Do not use estrogens, with or without progestins, to prevent dementia. Using estrogens, with or without progestins, may increase your risk of dementia
- Do not use estrogen products, including Divigel®, if you have unusual vaginal bleeding, currently have or have had certain cancers, had a stroke or heart attack in the past year, currently have or have had blood clots, currently have or have had liver problems, are allergic to any Divigel® ingredients, or think you may be pregnant

💧 The most common side effects for all estrogen products are headache, breast pain, irregular vaginal bleeding or spotting, stomach/abdominal cramps and bloating, nausea and vomiting, and hair loss. The less common but serious side effects include breast cancer, cancer of the uterus, stroke, heart attack, blood clots, dementia, gallbladder disease, and ovarian cancer

💧 In Divigel® clinical trials, the most common side effects were inflammation of the nasal passages and pharynx, upper respiratory tract infection, vaginal yeast infection, breast tenderness and vaginal bleeding. Call your healthcare provider right away if you have any symptoms that concern you

💧 Estrogen products should be used at the lowest dose possible for your treatment and only as long as needed. You and your healthcare provider should talk regularly about whether you still need treatment with Divigel®

💧 For more information, call **1-800-654-2299** or visit **www.divigel.com**

## Sources for Additional Information

This list includes several organizations that provide information about menopause. The content provided by these organizations is meant for informational purposes only and should not replace a physician's medical advice.

The American College of Obstetricians and Gynecologists  
**www.acog.com**

Food and Drug Administration  
US Department of Health and Human Services  
**www.fda.gov**

National Institute on Aging  
National Institutes of Health  
**www.nia.nih.gov**

National Women's Health Resource Center  
**www.healthywomen.org**

North American Menopause Society  
**www.menopause.org**

Office on Women's Health  
US Department of Health and Human Services  
**www.4women.gov/owh**

For more information,  
call **1-800-654-2299** or visit  
**www.divigel.com**



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*For more information on the  
Divigel<sup>®</sup> Patient Savings Program,  
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*Please see Patient Information  
within the enclosed  
Full Prescribing Information.*

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