



## Preferred Drug List

### NEW DRUG REVIEW

**Proprietary Name:** Divigel®

**Common Name:** Estradiol Gel

**PDL Category:** Estrogens - Patches

<u>Comparable Products</u>	<u>Preferred Drug List/ Recommended Drug List Status</u>
Elestrin™	Non-Preferred
Estraderm®	Preferred
Vivelle Patch/Dot®	Preferred

#### Summary

**Indications and Usage:** Moderate-to-severe vasomotor symptoms

**Mechanism of Action:** Binds to estrogen receptors in estrogen-responsive tissues to maintain gender characteristics and reproductive system

**Dosage Forms:** Gel, 0.25mg, 0.5mg, and 1mg packets

**Recommended Dosage:** Apply contents of packet on the skin of the upper thigh in a 5 x 7 inch area once daily; women with an intact uterus should combine Divigel® with a progestin product to reduce endometrial cancer risk

**Common Adverse Drug Reactions:** Breast tenderness, metrorrhagia, nasopharyngitis, URI

**Contraindications:** Undiagnosed abnormal genital bleeding, history of breast cancer, history of estrogen-dependent neoplasia, history of or active DVT or pulmonary embolism, active or recent arterial thromboembolic disease, hepatic dysfunction, hypersensitivity to any ingredients of the compound, known or suspected pregnancy

**Manufacturer:** Upsher-Smith Laboratories, Inc.

**Analysis:** Divigel® delivers sustained circulating concentrations of estradiol by way of a clear, odorless gel. The product is derived from plant sources making it identical to estrogen naturally produced in the body. Clinical studies document a dose dependent response that reduces both the frequency and severity of daily hot flashes. At the time of the product's release, Divigel® had only been compared to placebo. When compared to other preferred, topical estradiol products on the Preferred Drug List (PDL), Divigel® requires daily application and is only indicated for vasomotor symptoms whereas other products are dosed twice weekly and are indicated for treatment of other menopausal symptoms as well making them more cost effective. Therefore, it is recommended that Divigel® be added to the PDL as a non-preferred drug.

**IME Recommendation:**

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|---|---|
| <input type="checkbox"/> Preferred Drug                 | <input type="checkbox"/> Recommended Drug     |
| <input checked="" type="checkbox"/> Non-Preferred Drug  | <input type="checkbox"/> Non-Recommended Drug |
| <input type="checkbox"/> Preferred Drug with Conditions |   |