



# Menopausal Hormone Therapy Shortage

For the current status of drug shortages and discontinuations, refer to Drug Shortages Canada at [www.drugshortagescanada.ca](http://www.drugshortagescanada.ca).

TABLE 1: Selected estrogen products marketed in Canada<sup>1</sup>

| Product         | Active Ingredient, Formulation                 | Strength | DIN                              | Manufacturer                |
|-----------------|--|----------|----------------------------------|-----------------------------|
| Climara         | 17-beta estradiol, patch                       | 25 mcg   | 02247499                         | Bayer Incorporated          |
|                 |  | 50 mcg   | 02231509                         |                             |
|                 |  | 75 mcg   | 02247500                         |                             |
| Divigel         | 17-beta estradiol, gel                         | 0.1%     | 02424835<br>02424843<br>02424924 | Searchlight Pharma Inc.     |
| Estradiol Derm  | 17-beta estradiol, patch                       | 50 mcg   | 02246969                         | Sandoz Canada Inc.          |
|                 |  | 75 mcg   | 02246967                         |                             |
|                 |  | 100 mcg  | 02246968                         |                             |
| Estradot        | 17-beta estradiol, patch                       | 25 mcg   | 02245676                         | Sandoz Canada Inc.          |
|                 |  | 37.5 mcg | 02243999                         |                             |
|                 |  | 50 mcg   | 02231509                         |                             |
|                 |  | 75 mcg   | 02247500                         |                             |
|                 |  | 100 mcg  | 02244002                         |                             |
| Estrogel        | 17-beta estradiol, gel                         | 0.06%    | 02238704                         | Organon Canada Incorporated |
| Lupin-Estradiol | 17-beta estradiol, tablet                      | 0.5 mg   | 02449048                         | Lupin Pharma Canada Limited |
|                 |  | 1 mg     | 02449056                         |                             |
|                 |  | 2 mg     | 02449064                         |                             |
| Oesclim         | 17-beta estradiol, patch                       | 25 mcg   | 02243722                         | Searchlight Pharma Inc.     |
|                 |  | 50 mcg   | 02243724                         |                             |
| Premarin        | conjugated estrogens, sustained-release tablet | 0.3 mg   | 02414678                         | Pfizer Canada               |
|                 |  | 0.625 mg | 02414686                         |                             |
|                 |  | 1.25 mg  | 02414694                         |                             |



TABLE 2: Selected estrogen/progestin combination products marketed in Canada<sup>1</sup>

| Product                 | Active Ingredient, Formulation                      | Strength                     | DIN                  | Manufacturer             |
|-------------------------|---|------------------------------|----------------------|--------------------------|
| Activelle LD, Activelle | estradiol hemihydrate/norethindrone acetate, tablet | 0.5 mg/0.1 mg<br>1 mg/0.5 mg | 02309009<br>02249405 | Novo Nordisk             |
| Angeliq                 | 17-beta estradiol/drospirenone, tablet              | 1 mg/1 mg                    | 02268825             | Bayer Incorporated       |
| Bijuva                  | estradiol hemihydrate/progesterone, capsule         | 1 mg/100 mg                  | 02505223             | Knight Therapeutics Inc. |
| Estalis                 | 17-beta estradiol/norethindrone acetate, patch      | 140/50 mcg<br>250/50 mcg     | 02241835<br>02241837 | Sandoz Canada Inc.       |

## Health Canada–approved indications for estrogen and estrogen/progestin hormone therapy:<sup>2</sup>

- The relief of menopausal and postmenopausal symptoms occurring in naturally or surgically induced estrogen-deficiency states
- The prevention of osteoporosis in naturally occurring or surgically induced estrogen-deficiency states in addition to other important therapeutic measures such as adequate diet, calcium and vitamin D intake, cessation of smoking, and regular weight-bearing exercise

Common off-label uses of estrogen and estrogen/progestin hormone therapy:

- Estradiol formulations can be used in transgender and gender-diverse patients who may benefit from feminizing hormone therapy as part of their gender-affirming care<sup>3</sup>
- Add-back hormone therapy to mitigate perimenopausal symptoms and bone loss in patients receiving gonadotropin-releasing hormone (GnRH) agonists (e.g., endometriosis, heavy menstrual bleeding)<sup>4</sup>

## Management options:<sup>5</sup>

Menopausal hormone therapy (MHT) is the most effective treatment for vasomotor symptoms of menopause (VMS) in patients who are <60 years of age and <10 years postmenopause and have no MHT contraindications.<sup>6</sup>

Transdermal estrogen products have some advantages over oral products, including a potentially lower risk of venous thromboembolism, and may be considered over oral estrogen in certain patient groups (e.g., patients with migraines, hypertension). There are 2 transdermal formulations of estrogen available in Canada: topical gel (e.g., EstroGel) and topical patches (e.g., Estradot).

The [systemic MHT equivalency table](#) developed by the Canadian Menopause Society is a general clinical guide for initiating or switching between estrogen and progestogen formulations used in menopause management.

Multiple factors can influence the selection of an alternative hormonal therapy agent, including cost, adherence and patient preference. A list of alternative hormonal therapy products is shown in Table 3. Clinicians should monitor for efficacy and safety when switching between MHT products and titrate doses accordingly. For individuals with an intact uterus switching from a combination systemic estrogen/progestogen product to a systemic estrogen product alone, a progestogen agent should be added to lower the risk of endometrial hyperplasia.

Nonhormonal medications can also be considered for the treatment of VMS in patients for whom MHT is undesirable or contraindicated. A list of nonhormonal medications used in the management of VMS is listed in Table 4.

Vaginal estrogen therapy can be used alone to treat genitourinary syndrome of menopause (GSM). It can also be added to systemic MHT to address vaginal symptoms despite using MHT.<sup>5</sup> Available forms of vaginal estrogen include creams, intravaginal tablets and estradiol-releasing vaginal rings. See Table 5.

Nonestrogen therapies can be used to relieve some symptoms of GSM, including vaginal dryness and dyspareunia.<sup>5</sup> A list of nonestrogen medication used in the management of GSM is listed in Table 6.

The information presented here is generalized, and patients should be assessed on an individual basis. Patient assessment requires professional knowledge and judgment beyond the scope of this document. Consult CPS Full Access or other references if required.

**TABLE 3: Alternative hormonal products<sup>5</sup>**

| Drug                                 | Dosage                               | Adverse Effects   |
|--------------------------------------|--------------------------------------|---|
| Conjugated estrogen/<br>bazedoxifene | 1 tablet (0.45 mg/20 mg)<br>daily PO | Breakthrough bleeding/spotting, nausea, bloating/water retention, chloasma.   |
| Tibolone                             | 2.5 mg daily PO                      | Breakthrough bleeding/spotting, nausea, gastrointestinal upset, fatigue, breast tenderness, bloating/water retention, increased appetite. |

TABLE 4: Alternative nonhormonal products used in the management of menopausal symptoms<sup>5</sup>

| Drug  | Dosage              | Adverse Effects   |
|---|---------------------|---|
| <b>Alpha<sub>2</sub>-adrenergic Agonist</b>         |                     |   |
| Clonidine   | 0.05 mg BID PO      | Dizziness, dry mouth, drowsiness, constipation.                                 |
| <b>Anticholinergic Agents</b>                       |                     |   |
| Oxybutynin  | 2.5–5 mg BID PO     | Dry mouth, constipation, tachycardia.   |
| Oxybutynin, extended-release                        | 15 mg daily PO      | Dry mouth, constipation, tachycardia.   |
| <b>Gamma-aminobutyric Acid Derivatives</b>          |                     |   |
| Gabapentin  | 300 mg TID PO       | Somnolence, dizziness.  |
| Pregabalin  | 150–300 mg daily PO | Somnolence, dizziness.  |
| <b>Neurokinin 3 Receptor Antagonist</b>             |                     |   |
| Fezolinetant  | 45 mg daily PO      | Abdominal pain, diarrhea, insomnia, back pain.                                  |
| <b>Selective Serotonin Reuptake Inhibitors</b>      |                     |   |
| Citalopram  | 10–20 mg daily PO   | Gastrointestinal upset, sexual dysfunction, weight gain.                        |
| Escitalopram  | 10–20 mg daily PO   | Gastrointestinal upset, sexual dysfunction, weight gain.                        |
| Paroxetine  | 10–20 mg daily PO   | Gastrointestinal upset, sexual dysfunction, weight gain.                        |
| <b>Serotonin-Norepinephrine Reuptake Inhibitors</b> |                     |   |
| Desvenlafaxine                                      | 50–100 mg daily PO  | Gastrointestinal upset, dry mouth, drowsiness, nervousness, sexual dysfunction. |
| Venlafaxine   | 37.5–75 mg daily PO | Gastrointestinal upset, dry mouth, drowsiness, nervousness, sexual dysfunction. |



**TABLE 5: Alternative vaginal estrogens<sup>5,7</sup>**

| Drug   | Dosage   | Adverse Effects                             |
|--|--|---|
| 17-beta estradiol vaginal tablet (Vagifem 10)                    | 10 mcg intravaginal tablet once daily for 2 wk then twice weekly   | Local burning, irritation, vaginal leakage. |
| 17-beta estradiol vaginal insert (Imvexxy)                       | 4 mcg intravaginal insert once daily for 2 wk then twice weekly; 10 mcg insert may be used if higher dose is needed for clinical response                    | Local burning, irritation, vaginal leakage. |
| 17-beta estradiol vaginal ring (Estring)                         | 1 ring Q3 months vaginally   | Local burning, irritation, vaginal leakage. |
| Conjugated estrogens (CE) vaginal cream (Premarin Vaginal Cream) | 0.5 g (0.3 mg CE) daily for 14 days, followed by 0.5 g (0.3 mg CE) 2–3 times weekly  | Local burning, irritation, vaginal leakage. |
| Estrone vaginal cream, 0.1% (Estragyn Vaginal Cream)             | Cyclic regimen: 0.5–4 g (0.5–4 mg) daily vaginally, 3 wk on followed by 1 wk off<br>Continuous regimen: 0.5–4 g (0.5–4 mg) daily vaginally, 2–3 times weekly | Local burning, irritation, vaginal leakage. |

**TABLE 6: Nonestrogen therapies in the management of genitourinary syndrome of menopause<sup>5,8,9</sup>**

| Drug                     | Dosage                                  | Adverse Effects  |
|--------------------------|---|--|
| Ospemifene oral tablet   | 1 tablet (60 mg) daily PO               | Hot flashes, vaginal discharge, muscle spasms, excessive sweating. |
| Prasterone vaginal ovule | 1 ovule (6.5 mg) daily PV               | Vaginal discharge.   |
| Vaginal lubricants       | PRN                                     | None.  |
| Vaginal moisturizers     | Used regularly (e.g., 2–3 times weekly) | None.  |

## References

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