

2nd Edition

Hormone Therapy Products Available in Canada for Treatment of Menopausal Symptoms



Physician Desk Reference

A clinical resource provided to you by



THE SOCIETY OF
OBSTETRICIANS AND
GYNAECOLOGISTS
OF CANADA

Unsupported Hormone Therapies

Custom-Compounded Bioidentical Hormone Therapy

SOGC DOES NOT support the use of custom-compounded bioidenticals.

Custom-compounded bioidenticals hormone therapy **ARE NOT** regulated by Health Canada.

Examples of custom-compounded bioidenticals:

- Bi-est cream
- Tri-est cream
- Estriol cream
- Progesterone cream
- DHEA (dehydroepiandrosterone) tablets

SOGC DOES support the North American Menopause Society statement on Bioidentical Hormone Therapy:

“Concern arises with the bioidentical hormone medications that are “custom-compounded” (custom-mixed) recipes prepared by a pharmacist following an individual prescriber’s order for a specific treatment. These medications do not have [HEALTH CANADA] approval because individually mixed recipes have not been tested to prove that the active ingredients are absorbed appropriately or provide predictable levels in blood and tissue. Further, there is no scientific evidence about the effects of these compounded medications on the body—both good and bad.”

The Medical Letter Position (May 2010):

“There is no acceptable evidence that ‘bioidentical’ (custom-compounded) hormones are safe or effective. Patients should be discouraged from taking them.”

Prescribing Hormone Therapy

Physicians today have a wide selection of hormone therapies (HT) to choose from if HT is deemed necessary for the management of troublesome menopausal symptoms. This guide was developed to assist physicians in optimizing treatment decisions by summarizing some of the key information about all of the hormone therapies currently available in Canada. For complete information about the individual treatments reviewed in this guide, please consult the respective product monographs.

For more information about menopause, please consult the **SOGC Clinical Guideline, Menopause and Osteoporosis Update 2009**, available online at sogc.org and menopauseandu.ca.

Clinical Guidance¹

These are general recommendations that must be modified according to individual clinical situations and desires of the woman after she has been fully assessed and informed of all the available treatment options.

Contraindications to estrogen and progestogen use
Unexplained vaginal bleeding prior to investigation
Known or suspected breast carcinoma
Undiagnosed vaginal bleeding
Acute liver disease
Active thromboembolic disease (estrogen only)
Pregnancy

Use estrogen with caution	Use progestogen with caution
History of cardiovascular disease and hypertriglyceridemia	History of thromboembolic disorders
Risk of recurrence of breast cancer is unknown	

Reference:

¹ Reid RL, Blake J, Khan A, Abramson B, Fortier M, Senikas V. Menopause and Osteoporosis Update 2009. J Obstet Gynaecol Can 2009 Jan;31(1)(Suppl 1).

Estrogens, oral*

Product / Manufacturer	Type of Estrogen	Dosage / Strength and Administration	Clinical Indication(s)
ESTRACE Shire Canada Inc.	17 β -Estradiol	Tablet 0.5 mg 1 mg 2 mg (Daily)	<ul style="list-style-type: none"> • Symptomatic relief of menopausal symptoms • Adjunct to other therapeutics for the prevention of osteoporosis
PREMARIN Pfizer Canada Inc.	Conjugated equine estrogens	Tablet 0.3 mg 0.625 mg 1.25 mg (Daily)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms • Prevention of osteoporosis • Atrophic vaginitis • Vulvar atrophy • Hypoestrogenism due to hypogonadism
C.E.S. Valeant Canada Ltd.	Conjugated estrogens	Tablet 0.3 mg 0.625 mg 0.9 mg 1.25 mg (Daily)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms • Prevention and treatment of osteoporosis • Atrophic vaginitis • Hypoestrogenism due to hypogonadism

* No progestogen required in hysterectomized women.

Estrogens, transdermal*

Product / Manufacturer	Type of Estrogen	Dosage / Strength and Administration	Clinical Indication(s)
CLIMARA Bayer Inc.	17 β -Estradiol	Patch 0.025 mg 0.05 mg 0.075 mg 0.1 mg (Once weekly)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms • Prevention of osteoporosis (Climara 25 is not indicated for the prevention of osteoporosis)
ESTRADERM Novartis Pharmaceuticals Canada Inc.	17 β -Estradiol	Patch 0.025 mg 0.1 mg (Twice weekly)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms • Prevention of osteoporosis
ESTRADOT Novartis Pharmaceuticals Canada Inc.	17 β -Estradiol	Patch 0.025 mg 0.0375 mg 0.05 mg 0.075 mg 0.1 mg (Twice weekly)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms • Prevention of osteoporosis

* No progestogen required in hysterectomized women.

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Estrogens, transdermal* (continued from page 4)

Product / Manufacturer	Type of Estrogen	Dosage / Strength and Administration	Clinical Indication(s)
ESTROGEL Merck Canada Inc.	17 β -Estradiol	Gel 0.06% 2.5 g/2 pumps (Daily)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms • Atrophic vaginitis
OESCLIM Triton Pharma Inc.	17 β -Estradiol	Patch 0.025 mg 0.05 mg (Twice weekly)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms

* No progestogen required in hysterectomized women.

Estrogens, vaginal**

Product / Manufacturer	Type of Estrogen	Dosage / Strength and Administration	Clinical Indication(s)
ESTRAGYN VAGINAL CREAM Triton Pharma Inc.	Estrone	Cream 1mg/g 2-4g/applicator Supplied in tube of 45 g (Daily)	<ul style="list-style-type: none"> • Atrophic vaginitis • Kraurosis vulvae • Pruritus vulvae
ESTRING Paladin Labs Inc.	17 β -Estradiol	Silastic ring 2.0 mg (Continuous use for 3 months)	<ul style="list-style-type: none"> • Postmenopausal urogenital complaints due to estrogen deficiency such as: <ul style="list-style-type: none"> - Atrophic vaginitis - Dyspareunia - Dysuria - Urinary urgency
PREMARIN Pfizer Canada Inc.	Conjugated estrogens	Cream 0.625 mg/g 0.5-2 g/applicator Supplied in tubes of 14 g (Daily)	<ul style="list-style-type: none"> • Atrophic vaginitis • Dyspareunia • Kraurosis vulvae
VAGIFEM[†] Novo Nordisk Canada Inc.	17 β -Estradiol	Tablet 0.025 mg <i>Initial dose:</i> 1 tablet daily for two weeks <i>Maintenance dose:</i> 1 tablet twice weekly with 3-4 day interval	<ul style="list-style-type: none"> • Symptoms of atrophic vaginitis due to estrogen deficiency

**Addition of a progestogen is not required.

(continued on page 6)

[†] Will no longer be supplied by the manufacturer after December 30, 2011.

Estrogens, vaginal** (continued from page 5)

Product / Manufacturer	Type of Estrogen	Dosage / Strength and Administration	Clinical Indication(s)
VAGIFEM 10 Novo Nordisk Canada Inc.	17β -Estradiol	Tablet 0.01 mg <i>Initial dose:</i> 1 tablet daily for two weeks <i>Maintenance dose:</i> 1 tablet twice weekly	<ul style="list-style-type: none"> • Symptoms of vaginal atrophy due to estrogen deficiency

**Addition of a progestogen is not required.

† Will no longer be supplied by the manufacturer after December 30, 2011.

Progestogens, oral

Product / Manufacturer	Type of Progestogen	Dosage / Strength and Administration	Clinical Indication(s)
PROMETRIUM Merck Canada Inc.	Micronized progesterone	Tablet 100 mg (Daily)	For women with intact uteri: adjunct to postmenopausal estrogen replacement therapy to significantly reduce the risk of endometrial hyperplasia and carcinoma
PROVERA Pfizer Canada Inc.	Medroxyprogesterone acetate	Tablet 2.5 mg 5 mg 10 mg (Daily)	For women with intact uteri: adjunct to postmenopausal estrogen replacement therapy to significantly reduce the risk of endometrial hyperplasia and carcinoma

Combined estrogens and progestogens, oral

Product / Manufacturer	Type of Estrogen and Progestogen	Dosage / Strength and Administration	Clinical Indication(s)
ACTIVELLE Novo Nordisk Canada Inc.	Estradiol (as hemihydrate) Norethindrone acetate (NETA)	Tablet 1 mg Estradiol + 0.5 mg NETA (Daily)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms • Vulvar or vaginal atrophy
ACTIVELLE LD Novo Nordisk Canada Inc.	Estradiol (as hemihydrate) Norethindrone acetate (NETA)	Tablet 0.5 mg Estradiol + 0.1 mg NETA (Daily)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms

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Combined estrogens and progestogens, oral (continued from page 6)

Product / Manufacturer	Type of Estrogen and Progestogen	Dosage / Strength and Administration	Clinical Indication(s)
ANGELIQ Bayer Inc.	17 β -Estradiol Drospirenone (DRSP)	Tablet 1 mg Estradiol + 1 mg DRSP (Daily)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms • Atrophic vaginitis • Vulvar atrophy
femHRT Warner Chilcott Canada Co.	Ethinyl estradiol (EE) Norethindrone acetate (NETA)	Tablet 5 μ g EE + 1 mg NETA (Daily)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms • Atrophic vaginitis • Vulvar atrophy • Prevention of osteoporosis

Combined estrogens and progestogens, transdermal^{*}**

Product / Manufacturer	Type of Estrogen and Progestogen	Dosage / Strength and Administration	Clinical Indication(s)
CLIMARA PRO Bayer Inc.	17 β -Estradiol Levonorgestrel (LNG)	Matrix patch 45 μ g Estradiol + 15 μ g LNG (Once weekly)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms
ESTALIS Novartis Pharmaceuticals Canada Inc.	17 β -Estradiol Norethindrone acetate (NETA)	Patch 50 μ g Estradiol + 140 μ g NETA 50 μ g Estradiol + 250 μ g NETA (Twice weekly)	<ul style="list-style-type: none"> • Relief of menopausal and postmenopausal symptoms • Atrophic vaginitis • Vulvar atrophy

^{***} Recommended only in patients with an intact uterus since the regimen includes a progestogen whose role is to prevent endometrial hyperplasia.

Reference:

1. Health Canada Product Monographs. Available at: <http://webprod3.hc-sc.gc.ca/dpd-bdpp> (accessed August 2011).

**For more information
on women's health issues
consult:**

sogc.org

menopauseandu.ca

sexualityandu.ca

endometriosisinfo.ca

hpvinfo.ca



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