

Health Canada Approves First Low Dose Treatment Option to Help Women Better Manage Menopause

~ The LOWdown on menopause: More than 90 per cent of women aged 40 to 60 won't let symptoms get in the way of life¹ ~

Mississauga, ON – June 17, 2008 – Ninety per cent of Canadian women aged 40 to 60 feel that managing symptoms associated with menopause is important, according to a recent survey; however, 40 per cent have done nothing to manage their symptoms.² Commonly reported symptoms including hot flushes, sleep disturbance and irritability/depression can affect daily functioning and quality of life at a time when women are more likely to feel empowered and excited about this new stage of life. Health Canada has approved Activille[®] LD (Estradiol / Norethindrone Acetate), the first low dose (combination estrogen and progestogen) hormone therapy (HT) to provide effective relief of hot flushes related to menopause, in one convenient tablet.

“Today’s women entering menopause don’t want their symptoms to slow them down; however, there has been a reluctance in the past for women to manage their symptoms using hormone therapy due to perceived risks,” said Wendy Wolfman, Associate Professor of Obstetrics and Gynaecology at the University of Toronto, and Director of the Menopause Unit at Mount Sinai Hospital. “New low dose treatment options with minimal side effects can effectively address symptoms related to menopause, and allow women to take control of their health.”

The use of the lowest effective HT dose for the treatment of menopause-related symptoms is recommended by expert associations and clinicians, including the Society of Obstetricians and Gynaecologists of Canada (SOGC) and the North American Menopause Society (NAMS). According to recent recommendations by the International Menopause Society (IMS), HT is considered the gold standard treatment for moderate to severe menopausal symptoms, and should be considered the first treatment option, in the absence of any contraindications.³

“Hormone therapy should be prescribed at the lowest effective dose to achieve relief of symptoms associated with menopause,” said Dr. Guylaine Lefebvre, President of the Society of Obstetricians and Gynaecologists of Canada (SOGC). The SOGC, one of the nation’s leading authorities on women’s health, supports Health Canada’s decision. “We are pleased that there is a new option available to Canadian women. With that, it is important that women speak with their physician to determine if hormone therapy is an option for them.”

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“We know so much more about hormone therapy than we did in 2002 when the Women’s Health Initiative raised concerns about the health effects of hormone therapy,” said Dr. Robert Reid, Professor of Obstetrics and Gynaecology and Chair of the Division of Reproductive Endocrinology and Infertility at Queen’s University. “Activelle LD provides the lowest effective combined estrogen and progestogen dose available in Canada, making it a new option both for women who are beginning hormone therapy, as well as for women looking to ‘step down’ to a lower dose.”

MENOPAUSE AND TODAY’S WOMEN SURVEY: KEY HIGHLIGHTS

- Forty per cent of those who have experienced symptoms have not done anything to manage these symptoms; however, the vast majority (91 per cent) said that they feel it is important to do so
- Fifty-nine per cent of women aged 40 to 60 have started experiencing or have been through menopause, and 64 per cent (even some who say menopause has not started yet for them) have experienced at least some symptoms
- Most women who have experienced symptoms associated with menopause have experienced physical symptoms (94 per cent) with hot flushes / night sweats (84 per cent) being the most common
- More than one-third (39 per cent) have experienced emotional symptoms including mood swings, irritability and/or depression
- While the majority of women are concerned that all symptoms of menopause will impact their life, difficulty concentrating causes the most concern (70 per cent)
- Fifty-four percent of women say they would be likely to consider a lower dose of HT if it comes with a recommendation from the SOGC

ABOUT ACTIVELLE® LD

Health Canada’s approval of Activelle *LD* was based in part on the findings from the Choice Study (Clinical Study on Hormone Dose Optimisation In Climacteric Symptom Evaluation), a six month double-blind, randomized, parallel-group, placebo-controlled, multi-centre trial to investigate the efficacy and safety of an ultra-low dose combination with 0.5 mg estradiol and 0.1 mg norethindrone acetate for treatment of menopausal symptoms.

The study found that Activelle *LD* produced a rapid and significant reduction in the frequency (70.9/week to 13.2/week, $p \leq 0.001$) and severity (mean change in severity score of 9.1, $p=0.001$) of moderate to severe hot flushes associated with menopause, and improvement in the Greene Climacteric Scale Score, as compared with placebo (mean total symptoms score from 18 to 8, $p =0.001$).

The study also demonstrated tolerability and minimal side effects in the majority of patients. Clinically important symptoms related to the breast (breast discomfort, breast pain and tenderness) were reported by only three per cent of actively treated women, which was the same percentage as in the placebo group.

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ABOUT MENOPAUSE

In Canada, women spend more than one-third of their lives in the postmenopausal era. Menopause is the permanent cessation of menstruation, which occurs when the ovaries no longer release an egg each month and therefore cease to produce the female sex hormones estrogen and progesterone. Menopause generally begins between the age of 48 and 52. It can also occur if a woman has had surgery to remove her ovaries or if chemotherapy, radiotherapy or HT causes ovarian failure. The post-menopausal period and its associated symptoms can last up to 15 years, depending on the individual.

Women in menopause have an increased risk of developing osteoporosis. During the first five years after menopause, three to five per cent of a woman's bone mass is lost each year, and an additional one to two per cent is lost each year following.

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References:

¹ Leger Marketing. Menopause and Today's Women. Online study of 800 Canadian women ages 40-60 living across the country. Surveys were conducted between May 15th and May 21st, 2008.

² Ibid.

³ Birkhäuser MH, Panay N, Archer DF, et al. Updated practical recommendations for hormone replacement therapy in the peri- and postmenopause. *Climacteric* 2008;1(1):108-123.