ENDOCEUTICS® RECEIVES HEALTH CANADA APPROVAL FOR INTRAROSA®

The first innovative drug for the treatment of vulvovaginal atrophy with prasterone

Quebec City, Canada, November 6th, 2019; Endoceutics is happy to announce the approval of INTRAROSA by Health Canada for the treatment of postmenopausal vulvovaginal atrophy. INTRAROSA is offered as a vaginal ovule containing 6.5 mg of prasterone.

The lack of sex hormones associated with menopause may cause the tissues of the vulva and vagina to become thin and dry. Prasterone is used to make sex hormones in the vagina. This medicine replaces the natural sex hormones that are lacking in some women. It may improve the symptoms of vulvovaginal atrophy such as vaginal dryness, pain during sexual activity (dyspareunia), irritation and itching.

It is estimated that over 50% of postmenopausal women suffer from the symptoms of vulvovaginal atrophy and that less than 10% of these women are treated with prescription medicines.

“The approval of INTRAROSA in Canada represents an important step for our company. We are proud of this achievement and we wish to thank all the contributors to this success for the benefit of postmenopausal women affected by vaginal atrophy,” commented Dennis Turpin, President and Chief Executive Officer of Endoceutics.

The Development of INTRAROSA

INTRAROSA was developed in Quebec by Endoceutics, a company founded by late Dr Fernand Labrie (1937-2019). INTRAROSA was approved in the US and in Europe in 2016 and 2018, respectively, and is commercialized there through strategic alliances with partners of choice. Endoceutics has ongoing discussions with different potential partners for the commercialization of INTRAROSA in Canada in order to make it available as soon as possible.

The efficacy of INTRAROSA on dyspareunia and vaginal dryness, two symptoms of vaginal atrophy due to menopause, as well as on three indicators of vaginal health (vaginal pH and percentage of parabasal and superficial cells), was shown in two pivotal 12-week placebo-controlled clinical trials. In another study, statistically significant beneficial effects were observed on parabasal and superficial cells and well as on vaginal pH after only two weeks of treatment.

INTRAROSA was granted approval by Health Canada without any serious warnings and precautions. The safety data for INTRAROSA were obtained from one single-center pharmacokinetic study and four multicenter 12-week, randomized, double-blind, placebo-controlled efficacy studies, as well as one 52-week safety study. The most frequent adverse reaction reported in clinical trials with INTRAROSA was vaginal discharge, which can be caused by the melting of the ovule and the expected increase in vaginal secretions. In addition, blood levels of prasterone and sexual hormones did not increase beyond the normal upper limits for postmenopausal women.[1]

Contraindications

INTRAROSA is contraindicated in women who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient or component of the container. For a complete listing, please refer to the product monograph.[1]

INTRAROSA is contraindicated in women with undiagnosed abnormal genital bleeding. Any postmenopausal woman with undiagnosed, persistent or recurring genital bleeding should be adequately evaluated to determine the cause before considering initiating treatment with INTRAROSA.[1]

About the Mechanism of Action of INTRAROSA

Prasterone, also known as dehydroepiandrosterone (DHEA), is a natural steroid compound, inactive by itself, with no estrogenic, androgenic or other hormonal activity. Following intravaginal administration, prasterone is transformed into estrogens and androgens inside the vaginal cells. The sex steroids made intracellularly are also inactivated locally inside these same cells.[1]

About INTRAROSA®

INTRAROSA is a vaginal ovule containing 6.5 mg of prasterone. It comes in blister packs of 28 ovules, with 6 reusable applicators. The recommended dose is one vaginal ovule inserted once a day at bedtime, using the provided applicator or fingers.

About Endoceutics®

Endoceutics, Inc. is focused on women's health and possesses manufacturing plants and equipment to manufacture drugs, as well as bioanalytical laboratories. Endoceutics also has the expertise for clinical development, registration and commercialization of its products. It also has a portfolio of drugs at various stages of development. Endoceutics' mission is to provide women the quality of life they deserve.
For more information, please visit www.endoceutics.com.

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1. INTRAROSA® product monograph (prasterone). Date of revision: October 30th, 2019