

October 23, 2019
Fuji Pharma Co., Ltd

Manufacturing and marketing approval succession for l'estroge^l 0.06%, treatment for menopausal disorders

We have come to an agreement with Shiseido Co., Ltd. [Head Office: Chuo-ku, Tokyo; Representative Director: Masahiko Uotani] (hereinafter referred to as Shiseido), to transfer the manufacturing rights and marketing approval in Japan of the hormone replacement therapy (HRT) product which they used to manufacture and market for menopausal treatment drug "l'estroge^l 0.06%" (generic name: Estradiol), due to our company signing a license agreement with the originator of this product, BESINS Healthcare, for the manufacturing and marketing of this product in Japan starting from January 1, 2020.

"l'estroge^l 0.06%" is an external gel containing estradiol, a female sex hormone, as an active ingredient. It is applied to arms to supplement female sex hormones in the body and improve menopausal syndrome. In Japan, Shiseido has developed the drug, and on October 2006, the drug was approved for the "indication use for vasomotor symptoms (Hot flush and sweating)" associated with menopausal syndrome and ovarian deficiency symptoms. On November 2011, Shiseido received additional approval for low-dosage maintenance therapy, and since 2012, the marketing of the product in Japan has been conducted by Fuji Pharma.

We will work with Shiseido to succeed in the smooth transfer of the manufacturing and marketing approval of "l'estroge^l 0.06%" Fuji Pharma will continue to provide product supplies and product information to meet medical needs, as well as promoting the proper use of l'estroge^l.

About BESINS Healthcare

BESINS Healthcare (or “BESINS”) is a privately owned global pharmaceutical company headquartered in Monaco and operations through over twenty fully-owned affiliated companies around the world. BESINS is a world leader in novel therapies for gynecology and andrology. BESINS, pioneer in transdermal gels, has developed several natural hormone-based therapies over the years including bioavailable natural progesterone for pregnant women and bioavailable natural testosterone for testosterone deficiency syndromes. Since 2016, Fuji Pharma manufacture and market BESINS’ proprietary UTROGESTAN® Vaginal Capsules 200mg” in Japan, for luteal replacement in assisted reproductive medicine. BESINS’ licensee Fuji Pharma is also currently conducting clinical-development studies using BESINS’ Utrogestan® 100 mg, an oral formulation of natural micronized progesterone, used to reduce menopausal syndromes in women in Japan. BESINS continue to be a leader in estradiol replacement therapy with the first transdermal gel marketed in Europe, Oestroge1®; For more information, please visit <https://www.besins-healthcare.com/products/#womens>. BESINS Healthcare products are trusted and prescribed by healthcare professionals in more than 100 countries around the world. For more information, please visit www.besins-healthcare.com.

For further information, contact

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