

The NHI Drug Price Listing and Launch of DINAGEST Tablets 0.5 mg, a Treatment for Dysmenorrhea

This material is an English translation of the press release issued on May 27, 2020 in Japanese, and the Japanese release is given priority regarding content and interpretation.

May 27, 2020

Mochida Pharmaceutical Co., Ltd. (Headquarters: Tokyo, Japan; President: Naoyuki Mochida; hereinafter, Mochida) announced that “DINAGEST Tablets 0.5 mg” (generic name: dienogest; development code: MJR-35), a therapeutic agent for dysmenorrhea, will be launched on May 28, 2020 as the NHI (National Health Insurance) Drug Price has been listed today.

DINAGEST Tablets 1 mg, a therapeutic agent for endometriosis, was licensed from Jenapharm, now a subsidiary of Bayer AG, and developed by Mochida. It has been marketed in Japan since 2008 and an additional indication, reduction of pain caused by adenomyosis, was also approved in 2016.

As dienogest selectively activates progesterone receptors so as to inhibit ovarian function and proliferation of endometrial cells, Mochida developed it in anticipation of its effectiveness for dysmenorrhea, and in January 2020, obtained marketing approval for a low-dose formulation specifically for dysmenorrhea, “DINAGEST Tablets 0.5 mg”.

With DINAGEST Tablets 1 mg, Mochida has contributed to the treatment of patients with endometriosis or adenomyosis. Mochida believes that the launch of DINAGEST Tablets 0.5 mg will contribute to improving the QOL of women troubled with dysmenorrhea.

【Reference】

Summary of DINAGEST Tablets 0.5 mg

Brand Name	: DINAGEST Tablets 0.5 mg
Generic Name	: Dienogest
Ingredients and Contents	: 0.5 mg dienogest per tablet
Indication	: dysmenorrhea
Dosage and Administration	: Usually, to adults, 1 mg of dienogest is orally administered daily in two divided doses, starting from day 2-5 of the menstrual cycle.
Package	: PTP:140 tablets (14 tablets×10)
NHI Drug Price	: 166.50 Yen per tablet
Approval Date	: January 23, 2020
NHI Drug Price Listing Date	: May 27, 2020
Launch Date	: May 28, 2020
Manufacturer/ Distributor	: Mochida Pharmaceutical Co., Ltd.

About Dysmenorrhea

Dysmenorrhea refers to pathological symptoms accompanied menstruation, such as lower abdominal pain, lower back pain, abdominal bloating, nausea, headache, fatigue and weakness, anorexia, irritation, diarrhea or depression during the menstrual period. According to a survey by the Health and Welfare Sciences Research* of women aged 20 to 49 years in Japan, menstrual pain, such as lower abdominal or lower back pain, which is a predominant symptom of dysmenorrhea, was observed in 78.6%. Of those surveyed, 32.8% required some sort of medical intervention for menstrual pain, and 12.2% visited a medical institution for the treatment of menstrual pain.

* "Prevention, diagnosis, and treatment for endometriosis in the perspectives of sexual and reproductive health" (2001); Study report for the Health and Welfare Sciences Research 2000