

Press Release

Nobelpharma Co., Ltd.

Notification of Additional Indication for Lunabell[®] Compound Tablets
- Now possible to prescribe for functional dysmenorrhea -

Nobelpharma Co., Ltd. (Headquarters: Chuo-ku, Tokyo; Jin Shiomura, CEO) has announced that the company obtained approval of additional indication for norethisterone ethinylestradiol compound tablets (Lunabell[®] Compound Tablets) to treat functional dysmenorrhea^{*1} on December 21.

Lunabell[®] Compound Tablets are a LEP (Low dose Estrogen Progestin) formulation developed by Nobelpharma Co., Ltd. with indication for dysmenorrhea that accompanies endometriosis, and have been sold by Nippon Shinyaku Co., Ltd. and Fuji Pharma Co., Ltd. since July 2008.

Nobelpharma Co., Ltd. conducted double blind placebo trials of Lunabell[®] Compound Tablets for functional dysmenorrhea, and the result was confirmation of a high degree of safety and excellent results in improving throbbing pain, so that the additional indication for functional dysmenorrhea was approved.

Functional dysmenorrhea is a type of dysmenorrhea (pain during menstruation) that does not clearly accompany a malady such as endometriosis. About 80% of average women suffer pain during menstruation. Approximately half (47.0%) of women that received examination in medical clinics were confirmed to have functional dysmenorrhea, and some women suffered difficulties in their daily lives despite taking pain killers^{*2}. Lunabell[®] Compound Tablets have been proven to be effective against such functional dysmenorrhea, and have received approval for additional efficacy, and should alleviate the symptoms of most women suffering during menstruation, and contribute to the improvement of their QOL (Quality of Life).

*1: Dysmenorrhea causes menstrual pain sufficient to interfere with daily life, and functional dysmenorrhea is a type that is not organic dysmenorrhea that accompanies such maladies as endometriosis or adenomyosis.

*2: Ministry of Health, Labour and Welfare FY2000 report on science research

Description of drug

Drug name: Lunabell[®] Compound Tablets

Production and sales: Nobelpharma Co., Ltd.

Approval number: 22000AMX01599000

Ingredients: One tablet:
1mg norethisterone, 0.035mg ethinylestradiol

Indications: dysmenorrhea that accompanies endometriosis
Functional dysmenorrhea

Dosage: One tablet daily on a set schedule for 21 days, then cease for 7 days.
Take the above dosage for a cycle of 28 days, then whether or not menstruation has ceased, take the dosage for the next cycle from the 29th day, and repeat in the same manner after that.

Manufacturing and sales approval date: April 16, 2008
December 21, 2010 (additional efficacy)

Date of NHI price listed: June 13, 2008

NHI price: ¥328.60 per tablet

Packaging: PTP 84 tablets (PTP 21 tablets x 4)
PTP 210 tablets (PTP 21 tablets x 10)

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