

PRESS RELEASE:

September 27, 2021
Fuji Pharma Co., Ltd.**Approval of F-meno[®], a natural progestogen drug, in Japan**

Fuji Pharma Co., Ltd. (hereafter “Fuji”) has announced today that a new drug application for F-meno[®] capsule 100mg (generic name: progesterone, developed name: FSN-011-01, hereinafter “F-meno[®]”), a natural progestogen drug, was approved in Japan on September 27. F-meno[®] is the first drug in Japan indicated for the prevention of endometrial hyperplasia upon administration of estrogen drug for menopausal disorders and ovarian deficiency symptoms.

In Japan, there has been no progestogen drug indicated for the prevention of endometrial hyperplasia upon administration of estrogen drug for menopausal disorders and ovarian deficiency symptoms. Combined-progestogen (progestin) drugs have been used without approved label. For this reason, when a development recruitment was announced by the “Review Committee on Unapproved or Off-label Drugs with High Medical Needs” led by the Ministry of Health, Labour and Welfare in 2010, Fuji applied for it and commenced development.

F-meno[®] is a new progestogen drug that is easily absorbed by oral administration as natural progestogen is micronized.

Fuji expects that F-meno[®] will provide a new hormone replacement therapy treatment option for menopausal disorder and ovarian deficiency symptoms, and will further contribute to well-being of women.

■F-meno[®] Capsules 100mg

Brand name	:	F-meno [®] Capsules 100mg
Generic name	:	Progesterone
Dosage form/content	:	Capsules / Containing 100mg per capsule
Indications	:	Prevention of endometrial hyperplasia upon administration of estrogen drug for menopausal disorders and ovarian deficiency symptoms
Dosage and administration	:	In combination with estrogen drug, choose one of the following: <ul style="list-style-type: none">• 100mg of progesterone will be orally administered once daily at bedtime starting on the day of initiation of estrogen therapy.• 200mg of progesterone will be orally administered once daily at bedtime from Day 15 to Day 28 of estrogen drug therapy on Day 1 as the starting day of estrogen therapy. This is defined as one cycle, and the cycle is repeated thereafter.

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<< Reference >>

Natural progesterone (oral drug product containing 100 mg of progesterone)

This natural progesterone drug product, containing progesterone as an active ingredient, was developed by Besins Healthcare (head office: Monaco) and has already been approved and marketed in at least 100 countries or regions including the US, UK, and France for the treatment of various diseases that require progesterone supplementation. The International Menopause Society and other societies suggest that natural progesterone has a low risk of causing breast cancer and thrombosis, and it is regarded as an extremely safe product.

Menopausal disorder

The female body is affected by a hormone (estrogen), and its secretion varies considerably depending on the age and reproductive stage of an individual. Various symptoms affecting physical and mental health manifest during the menopausal period, when the amount of estrogen secreted rapidly decreases at a particular age (45–55 years). These symptoms are collectively called “menopausal symptoms (disorder)”

Based on the results obtained from an Internet questionnaire survey* involving 3,888 female general consumers within the menopausal age (40–60 years old), it is estimated that more than half of the women in the menopausal age, approximately 7 million, exhibit menopausal symptoms.

*Report on the results of a survey on menopausal disorder and its symptoms: QLife

Hormone replacement therapy

Since the major cause of menopausal disorder is a decrease in estrogen levels, supplementation of estrogen can improve various menopausal symptoms, including hot flashes. This estrogen supplementation is called hormone replacement therapy. However, it has been confirmed that a single administration of estrogen-containing products increases the risk of developing endometrial cancer in women with a uterus. Thus, co-administration of progesterone has been established as a prophylaxis.