

User information

INGREDIENTS:

Each capsule of Femarelle® contains:

Fermented soybean extract:	322 mg
Flaxseed:	108 mg
Gelatin capsule:	100 mg

All ingredients are from non-genetically modified plants.

INTENDED USE:

Femarelle® is a natural health product used for the relief of menopausal symptoms (e.g. hot flashes, sleep disturbances), and for the support of bone health. It is recommended that Femarelle® be taken from the onset of menopausal symptoms and continue as long as symptoms persist. Femarelle® has been available worldwide since 2000, and since then women around the world have benefited from Femarelle®'s relief of menopausal symptoms and effect on bone health.

RECOMMENDED DOSE:

Femarelle® should be taken twice a day, one capsule in the morning and one in the evening. You may swallow the capsule with some water. Femarelle® can be taken with or without food. It is important that you take two capsules a day as this is the required dose for optimal benefit. If a dose is missed, a capsule should be taken as soon as you remember, and the regular dose schedule should then continue. There is no need to take a double dose to make up for a missed dose.

WHAT IS MENOPAUSE?

When a woman reaches her early forties there are fewer ovarian follicles left in the ovaries. As a result, ovulation occurs less frequently. Because the follicles produce much of the estrogen in the body, estrogen levels also begin to decline. Peri-menopause is the term used to describe the transition period between a woman's reproductive years and the time when menstruation ceases completely. During that time, hormone levels fluctuate and decline, often at an irregular pace. The hormonal shifts contribute substantially to the sense of physical, mental and emotional imbalance that may characterize a woman's experience of menopause.

Menopause is the term that represents the end of menstruation. Estrogen levels eventually decrease to the point where buildup of the uterus lining no longer occurs, resulting in cessation of menstruation and the onset of menopause. The majority of women experience natural menopause between the ages of 45 and 55. However, menopause can occur as early as the 30s, and as late the 60s. Menopause is a natural event, not a disease.

Femarelle® is a natural, plant-based selective estrogen receptor modulator (SERM), which provides relief of menopausal symptoms and supports bone health without having an undesired effect on the tissues of the breast or the uterus.

Femarelle® is produced by employing a unique manufacturing procedure; no harsh chemicals are added during the production process. It is subjected to rigorous and comprehensive microbiological and biochemical testing throughout the manufacturing process. This unique process increases the bioavailability of the beneficial active ingredients that are found in the soya bean. Femarelle® contains no estrogen and is not an isoflavone extract.

WHY IS FEMARELLE® RIGHT FOR YOU?

Studies with Femarelle® have shown that relief of menopausal symptoms (e.g. hot flashes, sleep disturbances) and a sense of overall well-being is usually experienced within the first month of treatment, with three out of four women reporting relief of their bothersome menopausal symptoms.

Once women reach menopause, the decline in estrogen accelerates the process of bone loss to between 2% and 4% a year. This process leads to low bone mass and structural deterioration of bone tissue, resulting in bone fragility and greater susceptibility to fractures, especially of the hip, spine, and wrist. Studies with Femarelle® have shown that patients may experience a positive effect on bone health by increasing the bone density in their hip and spine.

Femarelle® is therefore an appropriate safe and effective therapy for the relief of menopause symptoms and supports bone health.

CONTRAINDICATIONS:

You should not take Femarelle® if you are taking medications that affect estrogen receptor activity such as hormonal therapy, raloxifene, or tamoxifen, since simultaneous treatment will affect the efficacy of both products.

Since Femarelle® is derived from soy and flaxseed, do not take it if you are allergic to soybeans, soy products or flaxseed.

CAUTIONS AND WARNINGS:

- Keep out of reach of children.
- Not for use during pregnancy.
- Not for use during breastfeeding.
- Consult a health care practitioner if symptoms worsen.
- Discontinue use and consult a health care practitioner if you experience breast pain, discomfort and/or tenderness, or if you experience a recurrence of menstruation and/or uterine spotting.
- Capsules are individually sealed in blister packs. Do not use if seal is cut, torn or broken.
- Do not use beyond the expiry date on the blister pack.

DURATION OF USE:

Consult a health care practitioner for use beyond 1 year.

ADVERSE EVENTS:

No serious adverse events have been reported with Femarelle®. The adverse event incidence rate in general is very low. Your health care practitioner should be informed as soon as possible if you feel unwell while using Femarelle®.

STORAGE:

Keep under normal storage conditions.

For more information visit: www.femarelle.ca

References / Références :

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2. Genazzani A.R. Brain-Region responsiveness to DT56a (Femarelle) Administration on Allopregnanolone and Opioid Content in Ovariectomized Rats. *Menopause* 2009;16(5):1037-1043.
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9. Somjen D, Yoles I. DT56a (Femarelle): a Natural Selective Estrogen Receptor Modulator (SERM). *J. of Steroid Biochemistry & Molecular Biology* 2007;104:252-258.
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11. Nachtigall L., et al. The Selective Estrogen Receptor Modulator (SERM) DT56a (Femarelle), does not affect platelet reactivity in normal or thrombophilic menopausal women. *Menopause* 2011;18(3):285-288.
12. Labos G., Trakakis E. et al. Efficacy and safety of DT56a compared to hormone therapy in Greek postmenopausal women. *J Endocrinol. Invest.* 2013;36(7):521-526.

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