

Revised on March, 2020

Revised on February 2014 (Revision of description for insert contents)

Female hormone cream

Category-2 OTC medicines

BASTOMIN Follicle hormone preparation

You should read this written explanation before use. Please keep it so that you can read it when you need to.

BASTOMIN is an OTC medicine with follicle hormone (type of female hormone called estrogen) containing a combination of ethinylestradiol and estradiol. Follicle hormone is produced by the ovaries helps control “Femininity” and “Dryness” in women’s body. However, to decline the function of ovaries with ageing or stresses causes deficient secretion of follicle hormone. Rapid decline of secretion of follicle hormone causes various malaises such as hot flash, excessive sweating, nervousness, irritation, feeling of cold, and frigidity. Those symptoms are called “menopausal discomfort”.

Folic stimulating hormone is hardly secreted after menopause, it causes genital atrophic and bring difficult intercourse. BASTOMINE is cream which can supply a deficiency follicle hormone through the skin and can be expected to improve those symptoms. The product can replace follicle hormone by small amounts without hepatic metabolism.



Precautions

× **When not to use the product**

(If you do not follow these instructions, the current symptoms may worsen or adverse reactions/incidents are more likely to occur.)

1. This product should not be taken in the following persons.
 - 1) Persons who have had an allergic symptom to this product or its ingredients.
 - 2) Persons who use the product before, squeeze the ointment about 3mm from tube, apply on the thin-skinned area such as inner thigh, and have any reaction such as rash, redness, itch, swelling, or similar reactions in the next day of application of the product
 - 3) Persons have or have a history of thrombosis, endometriosis, stroke, heart disease, or kidney disease.
 - 4) Persons who received the diagnose as Estrogen-dependent malignant tumor (such as breast

cancer, endometrial cancer, ovary cancer). [Active ingredients of the product may accelerate progression of malignant tumors in breast and uterus if they are present]

- 5) Persons who or family have medical history of malignant tumor.
 - 6) Persons with uterine fibroids, diabetes, hypertension, epilepsy, or liver dysfunction.
 - 7) Persons who are during menstrual period, has unusual vaginal bleeding, or with vaginal discharge (discharge).
 - 8) Pregnant women or women suspected of being pregnant and nursing women.
 - 9) Children.
2. The products should not be used on the following parts:
 - 1) Eyes and periorbital area.
 - 2) Affected areas where injured, Eczema, contact dermatitis, Lesion with an inflammation, or purulence.
 3. This product should not be taken together with the following products:

Other medications containing any ingredients of this product.
 4. This product should not be taken together with the following foods:

Food containing Hypericum perforatum (St. John's wort), ipriflavone.
 5. Do not contact of the product to unintended user.
 - 1) After use the product, wash well your hands with soap and lukewarm water.
 - 2) Be careful not to contact the product to unintended user. In case of unintended contact, wash well as soon as possible.
 - 3) If it is possible to touch the applied area to unintended user, wash applied area well with soap and tepid water.
 6. Do not use for a purpose of contraception.
 - 1) It is strongly recommended to use adequate birth control method for contraception.
 - 2) Menstrual cycle may be influenced by use of the product. While using the product, do not use temperature method (Ogino method etc.) for contraception.

Consultation

1. The following persons should contact a physician, pharmacist, or registered salesperson for a consultation before use.
 - 1) Persons undergoing medical treatment from a physician(s).
 - 2) Persons who have experienced allergic symptoms (rash, redness, itching, rash swelling, etc.) associated with product, etc.
2. If the following symptoms are observed after using this product, these may be adverse reactions, so immediately discontinue the use, and show this document to your physician, pharmacist, or registered sales person for a consultation.

Affected area	Symptoms	Affected area	Symptoms
Skin	rash, redness, itching, rash swelling	Digestive system	nausea, vomiting, loss of appetite
Breast	Pain, strain tension	Others	headache, edema, dizziness

3. If drastic change(s) in menstrual cycle and appearance of menstrual blood occurs, immediately discontinue the use, and show this document to your physician, pharmacist, or registered sales person for a consultation.
4. If no improvement is seen after about more than two-week application, show this document to your physician, pharmacist, or registered sales person for a consultation.
5. With any misuse, immediately discontinue the use, and show this document to your physician, pharmacist, or registered sales person for a consultation.

Other precautions

It is recommended to have medical exams for breast and uterus before start using the product. For continuous application of the product, it is recommended to have routine medical exam for breast and uterus.

■ Indication ■

Female menopausal discomfort, missing ovary syndrome caused by insufficient follicle hormone secretion, female genital organ hypoplasia, amenorrhea, dysmenorrhea, unusual menstrual cycle, ovarian dysfunction, unusual uterine bleeding, lactation insufficiency, infertility, female sexual arousal disorder, sensitivity to the cold.

【Definition of terms】

Female menopausal discomfort: various dysautonomia symptoms such as rush of blood to head, hot flashes, glow, chills, irritation associated with decline the function of ovaries with ageing or stresses causes deficient secretion of follicle hormone.

■ Dosage and administration ■

Apply and rub well adequate amount of the product on the local area.

【Precautions】

- 1) Strictly follow the given dosage and administration.
- 2) Attention should be paid so that the medicine will not come into contact with eyes. If the medicine comes into contact with eyes, immediately rinse them with water or lukewarm water. If the symptoms are severe, seek an ophthalmologist for medical treatment.
- 3) Wash well your hand and fingers after application.

- 4) Keep applying area clean before application.
- 5) This product is only for external use.

■Additional information on dosage and administration■

- Apply once a day (after bath or before bedtime), or twice a day (morning and night). Squeeze out 1cm of the cream on fingertip and apply and rub well on the skin of arms, thighs, or waist.
- Start and continue application for two weeks from the last day of the menstruation and pause application until the next menstruation.
- Postmenopausal women or stop menstrual for a while due to irregular menstruation cycles, apply the product for two weeks, and pause application the next two weeks or more (do not use during pregnancy).
- For symptoms of genital area, rub the cream directly on vulva skin.
- Restart applying the cream if symptoms recurrently appear.

■Active Ingredients■

Per 100g of the ointment contains the following active ingredients:

Active Ingredients	Per 100g composition	Nature
Ethinylestradiol	0.02mg	synthesized follicle hormone
Estradiol	0.06mg	follicle hormone

Excipients: vaseline, stearyl alcohol, glyceryl monostearate, polyoxyethylene hydrogenated castor oil 60, propylene glycol, methyl paraoxybenzoate, propyl paraoxybenzoate.

■Precautions for storage and handling■

1. Store in a cool, low humidity place away from direct sunlight.
2. Keep out of reach of children.
3. Do not transfer the product to a different container. (It may lead to misuse or alter the quality of the product).
4. Do not use the product after the expiration date.
5. Do not touch the eyes or mucous membranes with hands attached this product.
6. If you have too much tube of it, do not return to the original tube.

— Where to call —

DAITO Pharmaceutical Co., Ltd. Healthcare customer service
 URL: <http://www.daito-p.co.jp/>
 E-mail: info@daito-p.co.jp
 Phone: +81-3-3953-2836
 Period of acceptance: 10:00 to 12:00, 13:00 to 16:00

(Excluding Sat., Sun., public holiday and nonbusiness day)

Produced and distributed by DAITO Pharmaceutical Co., Ltd.

624-2, Masazato-section (ARIA 207), Kawada-cho, Kofu-city, Yamanashi Prefecture, Japan