

Revised on March, 2020

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

Female hormone ointment

Category-2 OTC medicines

HIMEROS Follicle hormone preparation

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

HIMEROS 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. This product is ointment 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. The product should not be used by the following persons
 - 1) Persons who experienced allergic symptoms by the product or an ingredient of the product.
 - 2) Persons who use the product before, squeeze the ointment about 3mm from tube and mix with 1~2 drop(s) of water or lukewarm water, 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) Persons who are or may be pregnant or lactation.
 - 9) Children.
2. The products should not be used on the following parts:
 - 1) Eyes and area around eyes.
 - 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 the same ingredients as 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 tepid 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 by 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, swelling, 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
 - 1)

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.

■ Indications ■

Frigidity, female sexual arousal disorder, infertility, Female menopausal discomfort, female nervous breakdown.

【Definition of terms】

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

Female nervous breakdown: symptoms caused by disturbed hormone secretion due to excessive mental stress or prolonged unbalanced diet.

■ Dosage and administration ■

Take 0.5g of ointment (size of a soybean) on a fingertip, dissolve it with 1~2 drop (s) of water, and apply it on female genital mucous membrane. Apply 1-2 times per day.

【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 external use.

■ Additional information on dosage and administration ■

- Apply once a day (after bath or before going bed), or twice a day (morning and night). Squeeze out 3~7mm of the ointment on fingertip and mix it well with a few drops of water. Apply it on female genital mucus membrane (vagina).
- For fine adjustment of the dosage, start 3mm per day, and gradually increase dosage up to 0.5g/day (approximately 12mm twice a day) to find your optimal dosage.
- 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).
- 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: Sucrose, glycerin, lanoline, Vaseline.

■ Precautions for storage and handling ■

1. Store in a cool, dry place away from direct sunlight.
2. Keep out of reach of children.
3. Do not transfer the product to different container (It may lead to misused or loss of quality of the product).
4. Do not use the product after the expiration date.
5. Do not touch the eyes or mucous membranes (excluding the inside of vagina) with hands attached this product.
6. If you have too much tube of it, do not return to the original tube.
7. Wipe cleanly residual ointment on cap and screw after use to avoid smudge by color-changed residual ointment.

— 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