

Revised on September 2017 (Revision of HCMOO)

Male Hormone Ointment Category- 1 OTC medicines

TONOS[®] Male hormone preparation

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

TONOS is a combination drug of local anesthetics (ethyl amino- benzoate, procaine hydrochloride, dibucaine hydrochloride) and a male hormone, testosterone, as active ingredients.

A delayed ejaculation effect can be expected by the action of local anesthetic by rubbing gently and thoroughly the product on the corona glandes. In short, the male hormone is a compound that stimulates “manhood”.

The active ingredients are absorbed by gently rubbing on soft skin site (scrotal sac) and is expected to improve subvirile, reduced erection, involuntary ejaculation, and andromenopause symptoms caused by poor secretion of the hormone by aging.



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 experienced allergic symptoms by the product or an ingredient of the product.
- (2) Persons who use the product before, squeeze the ointment about 5mm 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 with an androgen-dependent tumor or a person who are suspected of an androgen-dependent tumor [for example, Prostate tumor, breast tumor (malignant)].
- (4) Woman.
- (5) Children (Under 15 years old)
- (6) Persons with a prostatic hypertrophy accompanied with dysuria.
- (7) Persons with 2.0 ng/ml or over of prostate specific antigen (PSA) for the results of prostate examination

(definite diagnosis shall be in accordance with a doctor).

Testosterone may progress prostate tumors. Therefore, male user should be aware of the following matters:

- a. The incidence of prostate tumor is growing in especially over 50 years old male, then it is necessary to undergo a prostate examination before the use of this product.
- b. If the person using this product continuously, who should to undergo a periodical examination.
- c. If there is an abnormality in the results of the examination, please immediately stop using this product, and consult a doctor or pharmacist.

(8) Persons who has the sleep apnea syndrome.

2. The products should not be used on the following parts:

- 1) Eyes and periorbital area, mucous (oral cavity, nasal cavity etc.).
- 2) Tip of penis (urethral orifice).
- 3) Affected areas where injured, Eczema, contact dermatitis, Lesion with an inflammation, or purulence.

3. Do not use medications or below during use of the product:

Medical supplies including the male hormone

4. 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.

Consultation

1. The following persons should contact a physician, pharmacist, or registered salesperson for a consultation before administration...

(1) Persons undergoing medical treatment from a physician.

(2) Persons with a prostate hypertrophy without dysuria.

(3) Persons who allergic symptoms(rash, redness, itching, swelling、 blister、 pimple)associated with drugs or cosmetics.

(4) Persons or their family who have experienced allergic symptoms before.

(5) Persons who received the following diagnosis from a doctor:

Severe heart disease, kidney disease, liver disease, hypertension or plethora.

2. If the following symptoms are observed after taking this drug, these may be adverse reactions, so immediately discontinue the use of this product, and show this document to your physician, pharmacist, or registered salesperson for a consultation.

Affected area	Symptoms
Skin	rash, redness, itching, swelling、 blister、 pimple

3. A physician or pharmacist should be consulted and being sure to take this instruction leaflet with you if there is no improvement after about one month of administration.

4. If there are misuse, these may be adverse reactions, so immediately discontinue the use of this drug, and show this document to your physician, pharmacist, or registered salesperson for a consultation.

■Indication■

Andropause symptoms, male sexual neurasthenia (early ejaculation, reduced erection, dysfunction of sexual organ, decreased libido, involuntary ejaculation, nocturnal emission, etc.)

[Explanations of terms]

「Andropause symptoms」 means various syndromes accompanied with decreased male hormone.

「Reduced erection」 in 「Male sexual neurasthenia」 means weakening of erectile function.

「Dysfunction of sexual organ」 means insufficient functions as a male sexual organ.

「Pollution」 means early ejaculation before sufficient erection.

■ Active ingredients and description ■

Thoroughly rub about 0.1 g (a red small bean size) of this product once-daily into the affected area or soft part of skin for andromenopause symptoms. If symptoms improved, make change to use every other day or twice weekly.

Directly rub to the sexual organ for male sexual neurasthenia (early ejaculation, decreased erection and etc.)

【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.

■ Detailed method of use (Recommended) ■

	Delaying of ejaculation time for such as early ejaculation	Improvement of symptoms such as weakened erection and sexual stamina
Length of extrusion on fingertip from the tube	5 mm/once	
Method of use	Rub 20-30 min. before action	Continue rubbing once daily
Site of administration	Glans (corona of glans penis)	Scrotum (testicles)

Precaution for use	Spread with thorough rubbing. Wash out with such as a soap or wipe out the rubbed site. Start with small dosage (erection may be weakened if local anesthetizers in this product excessively work)	Spread overall with rubbing. When an improvement was observed, reduce rubbing to every other day or about twice in a week
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The following active ingredients are contained in one hundred grams of this product.

Active ingredients	Per 100 g composition	Nature
Testosterone	1 g	Male hormone
Ethyl aminobenzoate	10g	Local anesthetic
Procaine hydrochloride	0.5 g	Local anesthetic
Dibucaine hydrochloride	1g	Local anesthetic
Diphenhydramine hydrochloride	0.5g	Antihistaminic

White petrolatum is contained as an additive.

■Precautions for storage and handling■

1. Store in a cool place, like in a refrigerator (under 15 degrees), 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 drug).
4. Do not use the product after the expiration date.
5. If you have too much tube of it, do not return to the original tube.

■Others■

To describe the legal labeling requirements, the container is larger than content. Therefore, some space is in there, however for quality control purpose, the nitrogen gas is charged into the container and we strictly manage the content.

— 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.

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