

(2018.6.22)

Revised: November 2017 (Revisions associated with revision of precautions)

Important: Read this document carefully before use and keep it for reference.**Category 2 Drug**

- For the treatment of minor skin conditions and injuries -

Oronine[®] H Ointment

Recommended Uses of Oronine H Ointment

- (1) For the treatment of acne or eruptions, gently apply a small amount of Oronine H Ointment to the affected area with a fingertip. Wipe off excess with a soft cloth or a piece of gauze.
- (2) For the treatment of minor cuts, abrasions, or puncture wounds, after cleaning the wound thoroughly, apply an appropriate amount of Oronine H Ointment. Oronine H Ointment serves to disinfect the wound and prevent infection.
- (3) For the treatment of minor burns, apply an appropriate amount of Oronine H Ointment to the burned area and then cover the area with a piece of gauze. Oronine H Ointment serves to prevent infection.
- (4) For the treatment of minor cuts from sharp objects such as knives or razors, apply an appropriate amount of Oronine H Ointment to the wound. Oronine H Ointment serves to prevent infection due to its disinfectant action.
- (5) For the treatment of athlete's foot, apply an appropriate amount of Oronine H Ointment to the affected area after bathing. To ensure maximum effectiveness, apply Oronine H Ointment every day. Oronine H Ointment is not effective for the treatment of wet athlete's foot.



- (6) For the treatment of jock itch, ringworm, tinea capitis, or pityriasis simplex, apply an appropriate amount of Oronine H Ointment to the affected area.



- (7) Oronine H Ointment can be carried with you while traveling or during outdoor activities, and is also a useful medication in the home.



- (8) For the treatment of chapped skin or chilblains, apply an appropriate amount of Oronine H Ointment to the affected area after washing or bathing or before going to bed.



PRECAUTIONS CONCERNING USE

Important precautions

(The following points should be strictly observed. Failure to do so may cause the condition to deteriorate or lead to adverse reactions.)

1. Oronine H Ointment should not be used in the following people:

People who have had an allergic symptom to this drug, its ingredients, or chlorhexidine.

2. Do not use Oronine H Ointment in the following instances.

- (1) On eczema (incl. sores and rash)
- (2) As a makeup use
- (3) On insect bites

Conditions that require consultation

1. The following people should consult a physician, pharmacist, or registered salesperson before using Oronine H Ointment.

- (1) People who are receiving treatment from a physician.
 - (2) People with a history of allergic symptoms (rash, redness, itching, irritated skin, etc.) associated with drugs, etc.
 - (3) People in whom the affected area is extensive.
 - (4) People with severe moistening or erosion.
 - (5) People with severe injuries or burns.
2. The following symptoms may be adverse reactions. If any of these symptoms are observed after use, immediately discontinue the use of Oronine H Ointment and consult a physician, pharmacist, or registered salesperson. Bring this document with you for reference.

Affected part	Symptoms
Skin	Rash, redness, itching, swelling, and dry, chapped skin.

The following serious symptoms may occur in rare cases. In such cases, immediately seek medical aid.

Name of symptoms	Symptoms
Shock (Anaphylaxis)	Itching of skin, urticaria, hoarseness, sneezing, itchy throat, breathing difficulties, palpitations, and clouding of consciousness may occur immediately after use.

3. If symptoms fail to improve after use for 5 or 6 days, discontinue the use of Oronine H Ointment and consult a physician, pharmacist, or registered salesperson. Bring this document with you for reference.

INDICATIONS

Acne, eruptions, pityriasis simplex, minor burns, chapped skin, chilblains, minor cuts,

dry athlete's foot, ringworm, jock itch, or tinea capitis.

DIRECTIONS

Apply ointment with gauze, absorbent cotton, etc., or with clean fingertips directly to the affected part, depending on the symptoms.

<Precautions>

- (1) Oronine H Ointment should be used in children under careful parental supervision.
 - (2) Avoid contact with the eyes. In the case of accidental contact, rinse the eyes thoroughly with clean, cool or lukewarm water. If a severe reaction occurs, immediately consult an ophthalmologist.
 - (3) Oronine H Ointment is intended for external use only.
 - (4) The affected area and surrounding skin should be thoroughly washed before application.
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INGREDIENTS

Oronine H Ointment is a hydrophilic ointment containing chlorhexidine gluconate.

Each gram of Oronine H Ointment contains the following active ingredients:

20% Chlorhexidine Gluconate Solution, 10 mg

Lauromacrogol, Polysorbate 80, Aluminum Potassium Sulfate, Macrogol, Glycerin, Olive Oil, Stearyl Alcohol, White Bees Wax, Petrolatum, Glyceryl Stearate (self emulsified type), fragrance, and Purified Water are included as inactive ingredients.

PRECAUTIONS FOR HANDLING AND STORAGE

- (1) Keep tightly sealed and store in a cool place away from direct sunlight.
- (2) Keep this product out of the reach of children.

- (3) To avoid misuse and to ensure quality, do not store Oronine H Ointment in other containers.
 - (4) Do not use the product after the expiration date indicated on the package and the container.
 - (5) Since bottle container is made of glass, do not subject the container to strong physical impact. It may damage the container, and injury may occur.
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If you experience any problems after using this product, please notify the store where you purchased the product or contact the office below:

Customer Service Office

Otsuka Pharmaceutical Co., Ltd.

2-9 Kanda Tsukasamachi, Chiyoda-ku, Tokyo 101-8535, Japan

Phone: 03-3293-3212 Please call between 09:00 and 17:00 (except for Saturdays, Sundays, and holidays).

Inquiries about Adverse Drug Reaction Relief System should be made to:

Pharmaceuticals and Medical Devices Agency (PMDA)

Phone: 0120-149-931 (toll-free, Japan)

http://www.pmda.go.jp/kenkouhigai_camp/index.html

The PMDA provides relief benefits for health damages such as diseases and disabilities requiring hospitalization that were caused by adverse effects of pharmaceuticals that were prescribed at hospitals and clinics as well as pharmaceuticals purchased at pharmacies, etc., even if such pharmaceuticals were properly used.

Distributed by:

Otsuka Pharmaceutical Co., Ltd.

2-9 Kanda Tsukasamachi, Chiyoda-ku, Tokyo, Japan

Manufactured and distributed by:

Otsuka Pharmaceutical Factory, Inc.

115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima, Japan

(This is an English translation of the package insert for Oronine H Ointment marketed in Japan which is prepared by Otsuka Pharmaceutical Factory, Inc.)