

This document is reference information about the products.
Please confirm a document attached to a product definitely.

Underline: Revised at February 2017.

FLUCORT f

Ointment

Class-2 pharmaceutical product:

Therapeutic agent for eczema and dermatitis;
synthetic adrenocorticosteroid; antibiotic ointment formulation; topical agent

Flucort® F is a therapeutic agent for skin diseases, and must therefore not be used as make-up or aftershave. If used in large doses or for prolonged periods, problems that may arise include acne and/or rash on the face or around the mouth, facial redness and/or swelling, ichthyosis, and hairiness, and particular care must therefore be taken when using this product on the face. Furthermore, Flucort® F must not be used indefinitely or unnecessarily once alleviation of symptoms has been achieved.

⚠ PRECAUTIONS

⊗ DON'Ts

[Failure to follow these precautions may worsen the clinical condition or cause adverse reactions.]

- Do not take if**
 - you have ever had an allergic reaction to this product
 - you have had an allergic reaction to any kind of antibiotics or adrenocorticosteroid
- Do not apply to the following areas**
 - Any area affected with chickenpox, athlete's foot, ringworm, etc.
 - Any area that is markedly oozing or sore
 - The eyes and surrounding areas
- Do not apply to a wide area of the face**
- Do not use as make-up or aftershave**
- Avoid prolonged use.**



CONSULTATION

- Consult a doctor, pharmacist or registered pharmacy before use if**
 - you are under the care of a doctor
 - you have ever had an allergic reaction to a medical product
 - you intend to use this product on the face, lips, or other part of the mucous membrane
 - you have a large area affected by the skin disease
 - you have deep cuts or severe burns
 - you are pregnant or suspected of being pregnant
 - you are elderly
- If any of the following symptoms occur after medication, they may be adverse reactions, so discontinue use immediately, and consult a doctor, pharmacist or registered pharmacy, showing**

this Package Insert:

Affected area	Symptoms
Skin	Rash/redness, itching, soreness
Skin with skin disease	Athletes' foot, ringworm, and other trichophytic symptoms; acne; suppurative symptoms; prolonged continuous irritation becoming white

- If the symptoms are not alleviated after 5 to 6 days of treatment, discontinue use of medication, and consult a doctor, pharmacist or registered pharmacy, showing this Package Insert**

INDICATIONS

- Symptoms associated with suppuration: Eczema, dermatitis, prickly heat, rash, frostbite, insect bites and stings, urticaria
- Suppurative skin diseases: Impetigo albostaphylogenes, facial carbuncles, folliculitis

DOSAGE AND ADMINISTRATION

Apply an appropriate amount topically to the area showing symptoms, once or several times per day.

<Precautions concerning dosage and administration>

- Strictly follow the DOSAGE AND ADMINISTRATION.
- Give to children under parental supervision.
- If this product is used for diaper rash, tight-fitting diapers and pants-type diapers with tight plastic seals should not be used.
- Avoid contact with latex rubber items.
- Avoid contact with eyes. In case of contact with eyes, rinse immediately with water or lukewarm water. Consult your eye doctor immediately if severe symptoms occur.
- This product is for external use only.

COMPOSITION

Each 1 g contains:

Ingredient	Content
Fluocinolone acetonide (Synthetic Adrenocorticosteroid)	0.25 mg
Fradiomycin sulfate (antibiotic)	3.5 mg (titer)

Additives: Paraben, polyethylene glycol laurate, propylene glycol, white beeswax, petrolatum

PRECAUTIONS FOR STORAGE AND HANDLING

- Close cap tightly and store in a cool and dry place, away from direct sunlight.
- Keep out of reach of children.
- Do not transfer or store in another container. (May lead to misuse or quality deterioration.)
- Do not use after the expiration date.



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FLUCORT f

Ointment

Class-2 pharmaceutical product:

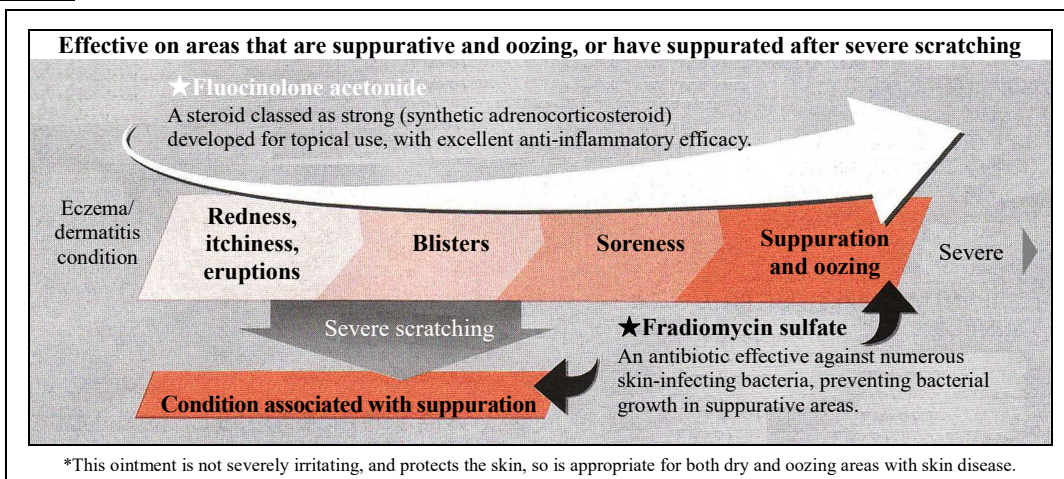
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**Correct understanding:
Correct treatment**

Skin problems such as eczema and dermatitis involve skin inflammation, with symptoms such as redness, swelling and itchiness. When the itchiness is severe, the sufferer may not be able to help scratching, but scratching leads to a vicious circle, as it irritates the skin, causing further inflammation, and thus more and more itchiness. If the sufferer does scratch the affected area severely, this prolongs the treatment period, and can leave scars even once the eczema or dermatitis has healed. Furthermore, bacteria can enter any open wounds on severely scratched areas, and their proliferation can lead to suppuration. It is therefore important for sufferers to undergo appropriate and reliable treatment soon after realizing that they have skin problems.



Fluocinolone acetonide combination with excellent anti-inflammatory —



STEROIDAL AGENTS (SYNTHETIC ADRENOCORTICOSTEROIDS)

WHAT ARE TOPICAL STEROIDAL AGENTS?

Adrenocorticosteroid is a hormone that is made inside the human body, and works by suppressing inflammation that occurs within the body. Synthetic adrenocorticosteroids are compounds that are based on adrenocorticosteroid, but have improved molecular structures and increased inflammatory activity. Synthetic adrenocorticosteroids that are substances for topical use are termed topical steroids, and those formulated for topical use are termed topical steroidal agents. Topical steroidal agents inhibit inflammation itself, in addition to suppressing symptoms such as redness, swelling and itchiness.

RANKING BY STRENGTH

Topical steroidal agents, including ethical pharmaceuticals, are placed in five classes on the basis of strength of efficacy, and topical steroidal agents belonging to three categories, “weak”, “Mild” and “strong”, are marketed as over-the-counter products. Fluocinolone acetonide is in the “strong” category.



ADVERSE REACTIONS

Synthetic adrenocorticosteroids have come to be used as orally administered medications for numerous inflammatory diseases, but the problem is that they sometimes result in systemic adverse reactions, such as suppression of adrenal function. To avoid this problem, topical steroidal agents which have only limited systemic effects, have been developed. Even topical steroidal agents can cause adverse reactions, such as thinning of the skin and dilation of dermal blood vessels, if used for prolonged periods. Furthermore, existing symptoms can be worsened if topical steroidal agents are used on areas of the skin with infections such as athlete’s foot. Please read carefully the “Cautions for Use” on this Package Insert, and use this product correctly.

We have set up a website, “Skin problem website: Eczema, rash and itchiness” (<http://www.hifunokoto.jp>), to help sound understanding and correct treatment of skin problems.

CORRECT ADMINISTRATION METHOD FOR TOPICAL STEROIDAL AGENTS FOR SELF MANAGEMENT

- Spread an appropriate amount* on the affected area, normally twice daily, but three times daily for severe symptoms.
- When the symptoms have been alleviated, continue treatment while reducing the frequency of administration.

* What is the appropriate dose?

Guide to the appropriate dose: Finger-tip units

If the tube is squeezed on to the tip of an adult’s index finger so as to reach to the first joint, the weight of the ointment is approximately 0.5 g, and this amount is sufficient to cover an area of skin approximately equal to the size of two adult palms. The amount of ointment used is decided on this basis, according to the size of the affected area.



The quantity covers approximately the area of the two spread palms of an adult.

- ✓ Do not use for more than 1 week.
- ✓ If the symptoms are not alleviated, or worsen, after use for 5 or 6 days, the skin disease may have a different cause, or it may be too severe for self-medication, and you should therefore consult a physician, pharmacist or registered pharmacy.
- ✓ If the affected area is more than the size of two or three of the palms of the person treated, the condition may be too severe for self-medication, and you should therefore consult a physician, pharmacist or registered pharmacy before use.