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CORT f[®] AT Ointment

Class-2 pharmaceutical product:

Therapeutic agent for eczema and dermatitis;
Synthetic adrenocorticosteroid; topical agent

In eczema and dermatitis, stimulation by foreign substances or allergic reactions cause inflammation of the skin, and in many cases, the affected area has redness, swelling and a rash with itching. **CORT f AT ointment** contains the topical steroid prednisolone valerate acetate (PVA), which gently suppresses "inflammation" the cause of such symptoms. This ointment type external preparation can be used for eczema and dermatitis in children with immature skin barrier function.

⚠ PRECAUTIONS

⊗ DON'Ts

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

1. Do not apply to the following areas

- (1) Chicken pox (varicella), athlete's foot, ringworm, etc. or suppurated site
- (2) Around eyes, mucosa, etc.

2. Do not apply to a wide area of the face

3. Avoid prolonged use.



CONSULTATION

1. Consult a doctor, pharmacist or registered pharmacy before use if

- (1) you are under the care of a doctor
- (2) you are pregnant or suspected of being pregnant
- (3) you have ever had an allergic reaction to a medical product
- (4) you have a large area affected by the skin disease
- (5) you have severe moistening or erosion

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

2. 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:

3. 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

Eczema, dermatitis, rash, itching, insect bite, heat rash, and hives

DOSAGE AND ADMINISTRATION

Apply an appropriate amount to the affected area several times a day.

<Precautions concerning dosage and administration>

- (1) Strictly follow the DOSAGE AND ADMINISTRATION.
- (2) Give to children under parental supervision.
- (3) 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.
- (4) This product is for external use only.

COMPOSITION

Each 1 g contains:

Ingredient	Content	Function
Prednisolone valerate acetate (synthetic corticosteroid hormone)	1.5 mg	Suppress inflammation and swelling of the skin.
Lidocaine	10 mg	Suppress itching and pain on the affected area.
Isopropyl methylphenol	1 mg	Disinfect the affected area.
Tocopherol acetate (vitamin E)	5 mg	Enhance blood circulation to accelerate the healing of symptoms.

Additives: Isopropyl myristate, cetostearyl alcohol, N-(hexadecyloxyhydroxypropyl)-N-hydroxyethyl hexadecanamide, liquid paraffin, petrolatum, and paraffin

PRECAUTIONS FOR STORAGE AND HANDLING

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



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CORT f[®] AT Ointment

Class-2 pharmaceutical product:

Therapeutic agent for eczema and dermatitis;
Synthetic adrenocorticosteroid; topical agent

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. It is therefore important for sufferers to undergo appropriate and reliable treatment soon after realizing that they have skin problems.



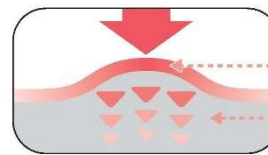
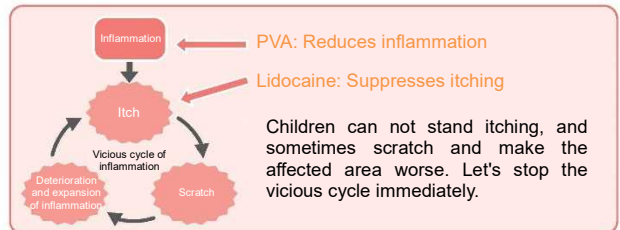
Containing topical steroid antedrug PVA with a mild effect

For treatment of eczema and dermatitis, it is important to choose a drug with sufficient efficacy to match the skin's barrier function, which differs mainly depending on the age.

In thin skin areas of adults and in skins of children, whose stratum corneum is immature and sebum secretion is low, because the barrier function of the skin is weak, medicines easily penetrate and you can expect sufficient anti-inflammatory effects even with mild topical steroids.

CORTfAT ointment contains the mild antedrug-type external topical steroid, prednisolone valerate acetate (PVA), and it is suitable for unbearable itching, eczema, and rashes on thin areas of adult skin and children's skin.

* The **CORTf** series has products with different anti-inflammatory activity and active ingredients.



<Image figure>

Exerts an effect on the affected area.
Is decomposed when absorbed.

Antidrugs exert their effects on the affected area and are degraded into less potent substances when absorbed in the body.

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

The CORTf series, which contains topical steroids, has three products with different anti-inflammatory activity and active ingredients. Prednisolone valerate acetate formulated in the CORTf AT ointment is a medium type topical steroid.



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

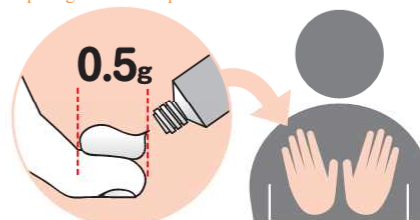
CORRECT ADMINISTRATION METHOD FOR TOPICAL STEROIDAL AGENTS FOR SELF MANAGEMENT

- 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, comparing the sizes of palms and 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 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. **(If the patient is a child, two or three palms of the child.)**