

PRESCRIBING INFORMATION

**Eczemus®**  
(Tacrolimus)

0.03% & 0.1% Ointment

ایگزیمس  
0.03% اور (0.1%) آئینٹمنٹ

**COMPOSITION**

**Eczemus 0.03% Ointment**

Each gram contains:  
Tacrolimus (as monohydrate) Brookes Specs..... 0.3 mg  
Mfg. Specs. Brookes

**Eczemus 0.1% Ointment**

Each gram contains:  
Tacrolimus (as monohydrate) Brookes Specs..... 1 mg  
Mfg. Specs. Brookes

**DESCRIPTION**

ECZEMUS (Tacrolimus) is a macrolide immunosuppressant produced by streptomyces tsukubaensis. It has been demonstrated that ECZEMUS (Tacrolimus) inhibits T-lymphocyte activation by first binding to an intracellular protein,FKBP-12. ECZEMUS (Tacrolimus) has also been shown to inhibit the release of inflammatory mediators from skin mast cells, basophils and eosinophils. ECZEMUS (Tacrolimus) ointment does not affect collagen synthesis in humans.

**INDICATION**

ECZEMUS (Tacrolimus) 0.03% Ointment is indicated for short-term and intermittent long-term therapy in the treatment of moderate to severe atopic dermatitis (eczema) in children.

ECZEMUS (Tacrolimus) 0.1% Ointment is indicated for short-term and intermittent long-term therapy in the treatment of moderate to severe atopic dermatitis (eczema) in adults.

**DOSAGE & ADMINISTRATION**

Apply ECZEMUS (Tacrolimus) Ointment twice a day, about 12 hours apart.

**Use in Children (age 2 to 15 years)**

Apply a thin layer of ECZEMUS (Tacrolimus) 0.03% Ointment to the affected skin areas twice daily and rub in gently and completely. Treatment should be continued for one week after clearing of signs and symptoms of atopic dermatitis.

**Use in Adults (16 years of age and above)**

Apply a thin layer of ECZEMUS (Tacrolimus) 0.1% Ointment to the affected skin areas twice daily and rub in gently and completely. Treatment should be continued for one week after clearing of signs and symptoms of atopic dermatitis.

**SIDE EFFECTS**

Burning sensation, pruritus and erythema were very common, usually mild to moderate in severity and tended to resolve within one week of starting treatment. Increased skin sensitivity and skin tingling were common skin irritation adverse reactions. Alcohol intolerance (facial flushing or skin irritation after consumption of an alcoholic beverage) is common.

**CONTRAINDICATION**

ECZEMUS (Tacrolimus) Ointment is contraindicated in patients with a history of hypersensitivity to Tacrolimus or any other component of the preparation.

**PRECAUTION**

Other topical preparations should not be applied to the same area within 2 hour of applying ECZEMUS (Tacrolimus) Ointment. Exposure of the skin to sunlight and sunlamp should be minimized. Avoid contact with eyes and mucous membranes.

**OVERDOSAGE**

ECZEMUS (Tacrolimus) Ointment is not for oral use. Oral ingestion of ECZEMUS (Tacrolimus) Ointment may lead to adverse effects associated with systemic administration of ECZEMUS. If oral ingestion occurs, medical advice should be sought.

**PREGNANCY AND LACTATION**

ECZEMUS (Tacrolimus) Ointment should be used during pregnancy only if the potential benefit to the mother justifies a potential risk to the fetus. It is known that ECZEMUS is excreted in human milk. Because of the potential serious adverse reactions in nursing infants from ECZEMUS, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**DRUG INTERACTION**

Formal topical drug interaction studies with ECZEMUS (Tacrolimus) Ointment have not been conducted. Systemic exposure from topical application of ECZEMUS Ointment is low. Based on its minimal extent of absorption, interactions of ECZEMUS Ointment with systemically administered drugs are unlikely to occur but cannot be ruled out. The concomitant administration of known CYP3A4 inhibitors in patients with wide spread and/or erythrodermic disease should be done with caution. Some examples of such drugs are erythromycin, itraconazole, ketoconazole, fluconazole, calcium channel blockers and cimetidine.

**STORAGE**

Store between 15 to 30 °C away from light.

**PRESENTATION**

ECZEMUS 0.03% Ointment is supplied in the tube of 10g

ECZEMUS 0.1% Ointment is supplied in the tube of 10g

مقدار اور طریقہ استعمال:

ایگزیمس آئینٹمنٹ کو ہر بار دھوئے بعد دن میں دو مرتبہ لگائیں

بچوں میں استعمال (2 سے 15 سال کی عمر)

متاثرہ جلد پر ایگزیمس (0.03%) آئینٹمنٹ دن میں دو مرتبہ لگائیں اور آہستہ سے مساج کریں۔

بڑوں میں استعمال (16 سال اور اس سے زیادہ)

متاثرہ جلد پر ایگزیمس (0.1%) آئینٹمنٹ دن میں دو مرتبہ لگائیں اور آہستہ سے مساج کریں

یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں

اسٹوریج:

15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی سے بچا کر رکھیں

**Brookes**

Manufactured by:

Brookes Pharma Private Limited  
58 - 59 Sector 15 Korangi Industrial Area  
Karachi 74900 Pakistan.

