

PM EXTERNAL- econazole nitrate, salicylic acid, lidocaine, l-menthol solution
OASIS TRADING

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ECONAZOLE NITRATE, SALICYLIC ACID, LIDOCAINE, L-MENTHOL

When left untreated, the symptoms can be painful, unsightly, and make walking difficult.

Here are the most common symptoms:

Itching or burning between your toes or on the soles of your feet

White, wet-looking skin in between your toes

Flaky skin or small tears (fissures) on feet or in-between toes

Red rash between the toes

Blisters or ulcers on the skin on top of foot

Broken blisters, causing pain and swelling

Thick, dry, scaly skin on the bottom and sides of feet

Keep out of reach of children

■ First wash and dry your feet thoroughly

■ Adults and children 2 years of age and older: apply to the affected area no more than 3 to 4 times daily

■ children under 2 years of age: consult a doctor

For external use only.

Flammable

■ Keep away from fire, flame, sparks and heated surfaces.

Tight cap firmly

Stop use and ask a doctor if

■ Condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days

When using this product

■ use only as directed

■ avoid contact with eyes

■ Do not apply to wounds or damaged skin

■ do not bandage tightly

If pregnant or breast-feeding, ask a health professional before use

keep out of reach of children.

acetone, chloroxylenol, water

For external use only

PM EXTERNAL SOLUTION

Drug Facts	
Active Ingredients (in 1mL)	Purpose
Econazole Nitrate 10mg -----	Antifungal
Salicylic Acid 100mg -----	Antifungal
Lidocaine 20mg -----	Antifungal
L-Menthol 20mg -----	Antifungal
Uses	
<ul style="list-style-type: none"> ■ When left untreated, the symptoms can be painful, unsightly, and make walking difficult. ■ Here are the most common symptoms: Itching or burning between your toes or on the soles of your feet White, wet-looking skin in between your toes Flaky skin or small tears (fissures) on feet or in-between toes Red rash between the toes Blisters or ulcers on the skin on top of foot Broken blisters, causing pain and swelling Thick, dry, scaly skin on the bottom and sides of feet 	
Warnings	
For external use only.	
Flammable	
<ul style="list-style-type: none"> ■ Keep away from fire, flame, sparks and heated surfaces. Tight cap firmly 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ■ Condition worsens or symptoms persist for more than 7days or clear up and occur again within a few days 	
When using this product	
<ul style="list-style-type: none"> ■ use only as direct ■ avoid contact with eyes ■ Do not apply to wounds or damage skin ■ do not bandage tightly 	
If pregnant or breast-feeding, ask a health professional before use	
Keep out of reach of children.	
Directions	
<ul style="list-style-type: none"> ■ First wash and dry your feet thoroughly ■ Adults and children 2 years of age and older: apply to the affected area no more than 3 to 4 times daily ■ children under 2 years of age: consult a doctor 	
Other Information	
<ul style="list-style-type: none"> ■ Store at room temperature 	
Inactive Ingredient	
acetone, chloroxylenol, water	
Questions or comments ?	
Call weekdays from 9 a.m to 5 p.m EST at (201) 669-8405	
Distributed By: P&K FRONTIER MARKETING CORP.	
329 BROAD AVENUE # 2F, PALISADES PARK, NJ 07650, USA	
Made in South Korea	

PM EXTERNAL

econazole nitrate, salicylic acid, lidocaine, l-menthol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72689-0038
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	20 mg in 1 mL
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	100 mg in 1 mL
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	20 mg in 1 mL
ECONAZOLE NITRATE (UNII: H438WYN10E) (ECONAZOLE - UNII:6Z1Y2V4A7M)	ECONAZOLE NITRATE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ACETONE (UNII: 1364PS73AF)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72689-0038-1	70 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/15/2018	

Labeler - OASIS TRADING (689991468)**Registrant** - OASIS TRADING (689991468)**Establishment**

Name	Address	ID/FEI	Business Operations
OASIS TRADING		689991468	manufacture(72689-0038)

Revised: 3/2019

OASIS TRADING