ZENOL MILD HOT- methyl salicylate, vanillyl nonylamide patch Lydia Co., Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Methyl salicylate

Vanillyl N-nonylamide (NONIVAMIDE)

Kaolin, Zine Oxide, Titanium Oxide, Galatin, Glycerin, Liquid Paraffin, Polybutene, Sodium Polyacrylate, Rubber Latex, Purified Water

For temporary relief of minor aches & pains of muscles & joints Associated with:

• Arthritis • Simple backache • Strains • Bruises • Sprains

keep out of reach of the children

Adults and children 12 years of age and over:

- •Clean and dry affected area •Remove patch from film
- •Apply to affected area not more than 3 to 4 times daily
- •Remove patch from the skin after at most 8-hour application

Children under 12 years of age:

use only as directed do not bandage tightly or use with a healing pad avoid contact with the eyes and mucous membranes do not apply to wounds or damaged skin

for external use only

ZENOL MILD HOT

Drug Facts

Active Ingredients

Purpose

Methyl Salicylate 105.0mg

Topical analgesic

Vanillyl Nonylamide 1.75mg

Topical analgesic

Uses For temporary relief of minor aches & pains of muscles & joints Associated with:

Arthritis
Simple backache
Strains
Bruises
Sprains

Warnings

For external use only

- · Use olny as directed
- Avoid contact with eyes, mucous membranes or rashes
- Do not bandage tightly

Keep out of the reach of children.

Directions

Adults and children 12 years of age and over:

- •Clean and dry affected area •Remove patch from film
- Apply to affected area not more than 3 to 4 times daily
- •Remove patch from the skin after at most 8-hour application

Children under 12 years of age:

consult a doctor

Other Information

Store at room temperature

Inactive Ingredient

Kaolin, Zine Oxide, Titanium Oxide, Galatin, Glycerin, Liquid

Paraffin, Polybutene, Sodium Polyacrylate, Rubber Latex, Purified Water

Questions or comments?

Call weekdays from 9 a.m to 5 p.m EST at (562) 273-0692

Distributed By: Bio Mission Group, Inc.

9925 Painter Ave Suite #O Whittier, CA90605, USA

Made in South Korea

NDC Number:

ZENOL MILD HOT

methyl salicylate, vanillyl nonylamide patch

Product I	nformation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72988-0025

Route of Administration TRANSDERMAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
NONIVAMIDE (UNII: S846B891OR) (NONIVAMIDE - UNII:S846B891OR)	NONIVAMIDE	1.75 mg in 14 g	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: 0414PZ4LPZ)	METHYL SALICYLATE	105 mg in 14 g	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
KAOLIN (UNII: 24H4NWX5CO)			
GLYCERIN (UNII: PDC6A3C0OX)			

l	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:72988- 0025-1	14 g in 1 POUCH; Type 0: Not a Combination Product	10/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2021	

Labeler - Lydia Co., Ltd. (695735569)

Registrant - Lydia Co., Ltd. (695735569)

Establishment					
Name	Address	ID/FEI	Business Operations		
Lydia Co., Ltd.		695735569	manufacture(72988-0025)		

Revised: 11/2021 Lydia Co., Ltd.