

NOPEN COOL- glycol salicylate, levomenthol patch
JW HOLDINGS CORPORATION

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.

NOPEN COOL

Active Ingredients (in each patch)

Glycol Salicylate 35mg

L-Menthol 35mg

Purpose

Topical Analgesic

Uses

Temporary relieves mild to moderate aches and pains of muscles and joints associated with:

■ simple backache ■ bruises ■ sprains ■ shoulder pains ■ muscle pains ■ arthritis

Warnings

For external use only

Do not use

■ on the face or rashes ■ wounds or damaged skin ■ with a heating pad ■ if you are allergic to salicylates
■ when sweating (Such as from exercise or heat) ■ on children under 12 years of age

Ask a doctor before use if

■ you have redness over the affected area ■ pregnant or breast feeding

When using this product

■ wash hands after applying or removing patch. ■ avoid contact with eyes or mucous membranes. ■ if eye contact occurs, rinse thoroughly with water. ■ do not bandage tightly

Stop use and ask a doctor if

■ rash, itching or skin irritation develops ■ condition worsens or symptoms persist for more than 7 days
■ symptoms clear up and occur again within a few days

Keep out of reach of children

Package not child-resistant. Dispose of the used patches after folding sticky ends together. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

■ clean and dry affected area before applying
■ peel off protective backing and apply sticky side to affected area and leave in place for up to 8 to 12

hours

- remove used patch from skin before applying a new patch

Other Information

- store at 20° to 25° (68° to 77°)
- avoid storing product in direct sunlight
- protect product from excessive moisture
- some individuals may not experience pain relief until several hours after applying the patch

Inactive ingredients

Acryl Adhesive, Nonwoven Polyester Fabric, Paper Release Liner, Rubber Adhesive, Vanillyl Butyl Ether

Questions or comments?

Call 1-562-281-5888 Monday-Friday 9AM-4PM ET

Distributed by: Jemian USA Inc

Principal Display Panel-5 Patches

JW Pharmaceutical

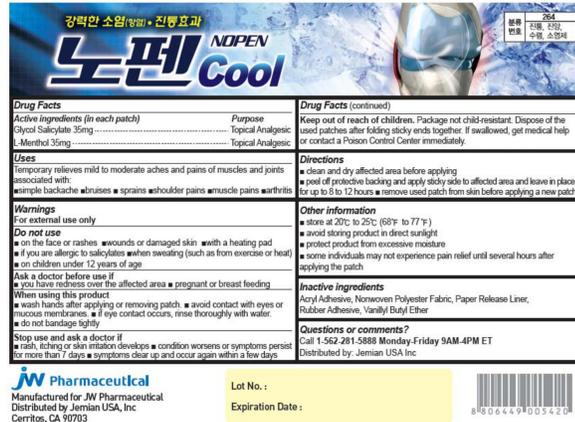
NOOPEN

Cool

Neutral sensation type Glycol Salicylate/ L-Menthol

5 Patches

2.7 in x 3.9 in (7 cm x 10 cm)



NOPEN COOL

glycol salicylate, levomenthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69365-006
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCOL SALICYLATE (UNII: 311VBB7AXH) (GLYCOL SALICYLATE - UNII:311VBB7AXH)	GLYCOL SALICYLATE	35 mg
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	35 mg

Inactive Ingredients

Ingredient Name	Strength
LOW DENSITY POLYETHYLENE (UNII: J245LN42AI)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
VANILLYL BUTYL ETHER (UNII: S2ULN37C9R)	
POLYETHYLENE TEREPHTHALATE (INTRINSIC VISCOSITY 0.70-1.00) (UNII: 645M2T7FHZ)	
PO WDERED CELLULOSE (UNII: SMD1X3XO9M)	

Product Characteristics

Color		Score	
Shape	RECTANGLE (2.7 in x 3.9 in (7 cm x 10 cm))	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69365-006-01	5 in 1 POUCH; Type 0: Not a Combination Product	08/17/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/17/2018	

Labeler - JW HOLDINGS CORPORATION (631094492)

Registrant - JW HOLDINGS CORPORATION (631094492)

Revised: 8/2018

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