TYLENOL PRECISE COOLING PAIN RELIEVING- lidocaine, menthol cream
Johnson & Johnson Consumer Inc.

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.

Tylenol Precise Cooling Pain Relieving Cream

Drug Facts

Active Ingredient

Lidocaine 4%..... Topical analgesic

Menthol 1%..... Topical analgesic

Purpose

Topical analgesic

Uses

For the temporary relief of pain

Warnings

For external use only.

Do not use

■ in large quantities, particularly over raw surfaces or blistered areas

When using this product

■ avoid contact with eyes

Stop use and ask a doctor if

■ 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. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- use only as directed

- adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other Information

store at 15 ° to 30 ° C (59 ° to 86 ° F)

Inactive Ingredients

carbomer copolymer, cetearyl olivate, cetyl alcohol, fragrance, glycerin, isopropyl palmitate, phenoxyethanol, sodium polyacrylate, sorbitan olivate, water

Questions?

Call **1-877-895-3665** (toll-free) or **215- 273-8755** (collect)

Distributed by:

JOHNSON & JOHNSON

CONSUMER INC.

Skillman, NJ 08558 USA

PRINCIPAL DISPLAY PANEL - 113 g

Cooling+

Pain Relieving Cream

Lidocaine 4% Menthol 1%

TYLENOL®

PRECISE ™

Fast acting +

Targeted

penetrating

pain relief

ROLLER BALL

APPLICATOR

Maximum Strength Lidocaine

without a prescription

LIGHTLY SCENTED

For external

use only

NET WT 4.0 OZ (113 g)

TYLENOL PRECISE COOLING PAIN RELIEVING

lidocaine, menthol cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69968-0793
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	10 mg in 1 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0793-1	1 in 1 CARTON	07/03/2023	
1		14.2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69968-0793-4	1 in 1 CARTON	07/03/2023	
2		113 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/03/2023	

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 5/2023 Johnson & Johnson Consumer Inc.