ZYLOTROL MAXIMUM PAIN PATCH- lidocaine 4%, menthol 1% patch
ASCLEMED USA INC.

Zylotrol for Pain Control Lidocaine 4% and Menthol 1%

Lidocaine 4%

Menthol 1%

Topical Analgesic

For external use only not intended for ingestion.

- in large quantities, particularly over raw surfaces, or blistered areas.
- Avoid contact with eyes.
- condition worsens, or if symtoms persist for more than 7 days or clear up and occur again within a few days.

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

ask a health professional before use.

DIRECTIONS

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times a daily.
- Children under 2 years of age: consult a doctor.
- Store at 20-25oC (68-77oF) and protect from moisture.

polyacrylamide, vinol, sodium polyacrylate; acrylate polymerization; purified water.

Questions?

(310) 320-0100

USES

For the temporary relief of pain.

ZYLOTROL MAXIMUM PAIN PATCH

lidocaine 4%, menthol 1% patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76420-144(NDC:81902-101)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
ETHENYL (UNII: PQ2K3G3591)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-144-15	15 in 1 BOX	08/20/2021	
1		4 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	07/30/2021	

Labeler - ASCLEMED USA INC. (059888437)

Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-144)

Revised: 10/2023 ASCLEMED USA INC.