ZYLOTROL MAXIMUM PAIN- lidocaine 4%, menthol 1% patch
Whitestone Products LLC

ZYLOTROL MAXIMUM PAIN PATCH

Active Ingredients

Lidocaine 4% w/w

Menthol 1% w/w

Purposes

Topical analgesic

Topical analgesic

Uses

For the temporary relief of pain.

Warnings

For external use only

Do not use:

- More than 1 patch at a time
- On wounds or damaged skin
- For more than one week without consulting a doctor
- If you are allergic to any ingredients of this product

When using this product:

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

Stop use and ask a doctor if:

- Localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling and blistering
- Condition worsen
- Symptoms persist for more than 7 days
- Symptoms clear up and occur again within a few days

If pregnant or breast-feeding,

Ask a health professional before use

Keep out of reach of children.

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

Directions

Adult and children 12 years of age and over:

- Clean and dry affected area
- Remove film from patch and apply to the skin (see illustration)
- Apply 1 patch at a time 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 68-77℉ (20-25℃)
- Store in a cool dry place away from direct sunlight

Inactive Ingredients

Water, Glycerin, Polyacrylic Acid, Propylene Glycol, Sodium Polyacrylate, Polysorbate 80, Mineral oil, Polyvinylpyrrolidone K90, Hydroxyacetophenone, L(+)-Tartaric Acid, Dihydroxyaluminium Aminoacetate, Edetate Disodium, Kaolin, Titanium Dioxide

Questions?

(310) 320-0100

Principal Display Panel

ZYLOTROL MAXIMUM PAIN

lidocaine 4%, menthol 1% patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81902-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.03 g in 3 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.12 g in 3 g

Inactive Ingredients	
Ingredient Name	**Strength**
KAOLIN (UNII: 24H4NWX5CO)	
TARTARIC ACID (UNII: W4888I119H)	
WATER (UNII: 059QF0KO0R)	

DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	

Product Characteristics

Color	brown	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81902-104-15	15 in 1 BOX	12/23/2022	
1		3 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)	12/23/2022	

Labeler - Whitestone Products LLC (118064415)

Revised: 10/2023 Whitestone Products LLC