ULTRA LIDO GEL PATCH- lidocaine patch Singular Dreamer, Ltd dba True Marker

Active Ingredient

Purposes

Lidocaine 4.00%Topical anesthetic

Uses

For temporary relief of pain.

Warnings

- For External Use only
- Do not use:

 More than 1 patch at a time

 On wounds or damaged skin
 With a heating pad
 If you are allergic to any ingredients of this product

When using this product:

Use only as directed

 Avoid contact with eyes, mucous membranes or rashes

 Do not bandage tightly

Stop use and ask a doctor if:

- Localized skin reaction occur, such as rash, itching, redness, irritation, pain, swelling and blistering ■ Condition worsens
 - 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 the 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
- 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 controlled room temperature 20° 25°C (68° 77°F)
- Avoid storing product in direct sunlight

Protect product from excessive moisture

Inactive Ingredients

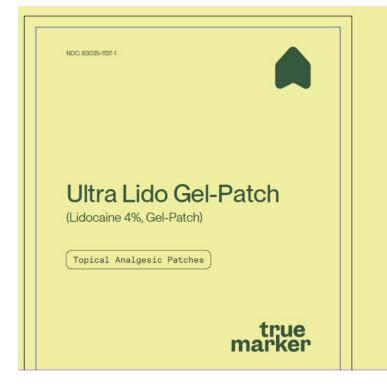
Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Carbomer, Cetearyl Alcohol, Ethylhexylglycerin, Glycol Stearate,

Glyceryl Stearate, Helianthus Annuus (Sunflower) Oil, Phenoxyethanol, Polysorbate-60, Simmondsia Chinensis (Jojoba) Oil, Stearic Acid, Triethanolamine.

Questions or Comments

Call 1-(888) 811-2634

Product label







ULTRA LIDO GEL PATCH

lidocaine patch

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83035-1137

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) LIDOCAINE 4 g in 100 g

Inactive Ingredients			
Ingredient Name	Strength		
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
GLYCERIN (UNII: PDC6A3C0OX)			
KAOLIN (UNII: 24H4NWX5CO)			
METHYLPARABEN (UNII: A218C7H19T)			
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)			
POLYSORBATE 80 (UNII: 60ZP39ZG8H)			
POVIDONE K90 (UNII: RDH86HJV5Z)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)			

TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (LINIII: 0590E0KOOR)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:83035- 1137-1	15 in 1 BOX	07/18/2024			
1		1 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	M017	07/18/2024		

Labeler - Singular Dreamer, Ltd dba True Marker (129504103)

Registrant - Singular Dreamer, Ltd dba True Marker (129504103)

Revised: 7/2024 Singular Dreamer, Ltd dba True Marker