

**LIDOCAINE WITH MENTHOL PATCH PAIN RELIEF- lidocaine 4% and menthol 1% patch**

**ONE2ZEE LIMITED LIABILITY COMPANY**

*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.*

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**LIDOCAINE WITH MENTHOL PATCH PAIN RELIEF- lidocaine 4% and menthol 1% patch**

**Active ingredient**

Lidocaine 4%

Menthol 1%

***Purpose***

Topical Anesthetic

***Uses***

Temporarily relieves minor pain associated with: arthritis, simple backache, bursitis, tendonitis, muscle strains, sprains & bruises.

***Warning***

**For external use only**

***Do not Use***

- more than 1 patch on your body at a time or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

***When Using This Product***

- use only as directed. Read and follow all directions and warnings on this label.
- do not allow contact with the eyes
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- do not use at the same time as other topical analgesics
- dispose of used patch in manner that always keeps product away from children or pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

***Stop Use and Ask a Doctor if***

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days

- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

***If Pregnant or Breast Feeding***

- ask a health professional before use.

***Keep Out of Reach of Children and Pets***

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

**Directions:**

**Adults and children over 12 years:**

- clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- use 1 patch for up to 12 hours

**children 12 years or younger:** ask a doctor

***Inactive Ingredients***

kaolin, polysorbate 80, polyacrylic acid, silicon dioxide, sodium polyacrylate, titanium dioxide

**Package / Principle Label**



## Package / Inner Pouch



# LIDOCAINE WITH MENTHOL PATCH PAIN RELIEF

lidocaine 4% and menthol 1% patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55629-061
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POLYACRYLIC ACID (250000 MW)</b> (UNII: 9G2MAD7J6W)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JN12J)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>	RECTANGLE	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-061-03	20 in 1 BOX	01/26/2021	
1	NDC:55629-061-01	1 in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	01/26/2021	

**Labeler** - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

**Registrant** - NE2ZEE LIMITED LIABILITY COMPANY (078656111)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
DR SABHARWAL'S WOUND CARE		862184668	manufacture(55629-061) , analysis(55629-061)

Revised: 1/2021

ONE2ZEE LIMITED LIABILITY COMPANY