

## **LIDOCAINE- lidocaine patch**

**Alexso, 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.*

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### **Lidocaine Patch**

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### **Lidocaine 4% Patch**

### ***Drug Facts***

#### **Active ingredient**

Lidocaine 4%

#### **Purpose**

External analgesic

#### **Uses**

Temporarily relieves pain and itching associated with:

- minor burns
- sunburn
- minor cuts
- scrapes
- insect bites
- minor skin irritations

#### **Warnings**

**For external use only.**

Read all warnings and directions before use.

## **Do not use**

- More than one patch at a time
- On wounds or damaged skin
- With a heating pad
- If you are allergic to any ingredients of this product

**Allergy Alert:** if you are allergic to any inactive ingredient of this product, contact a doctor before use.

## **When using this product**

- Use only as directed.
- **Avoid contact with eyes**, mucous membranes, or rashes
- Do not tightly wrap or bandage the treated area

## **Stop use and ask a physician:**

- If pregnant or breast feeding
- If localized skin reactions occur, such as rash, itching, redness, irritation, pain, swelling, and blistering
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician.

## **Keep out of reach of children and pets.**

If swallowed, get medical help or contact a Poison Control Center immediately.

## **Directions**

### **Adults and children 12 years of age and older:**

Apply 1 patch to the affected area of intact skin up to 3 times a day. Do not leave patch on for more than 8 hours at a time.

1. Clean and dry the affected area.
2. Open pouch and remove one patch.
3. Remove any protective film and apply directly to affected area of pain. Apply immediately after removal from the protective envelope.
4. Wash hands with soap and water after handling the patches.
5. Reseal pouch containing unused patches after each use. Do not store patch outside the sealed envelope.
6. Fold used patches so that the adhesive side sticks to itself and safely discard used patches or pieces of cut patches where children and pets cannot get to them.

**Children under 12 years:** Ask a physician

## **Other information**

Store at room temperature 15°-30°C (59°-86°F)

Avoid storing product in direct sunlight and protect product from excessive moisture.

## Inactive ingredients

Aqua (Deionized Water), Glycerin, Sodium Polyacrylate, Propylene Glycol, Polysorbate 80, Tartaric Acid, Dihydroxyaluminium Aminoacetate, Methylparaben, Peppermint Oil

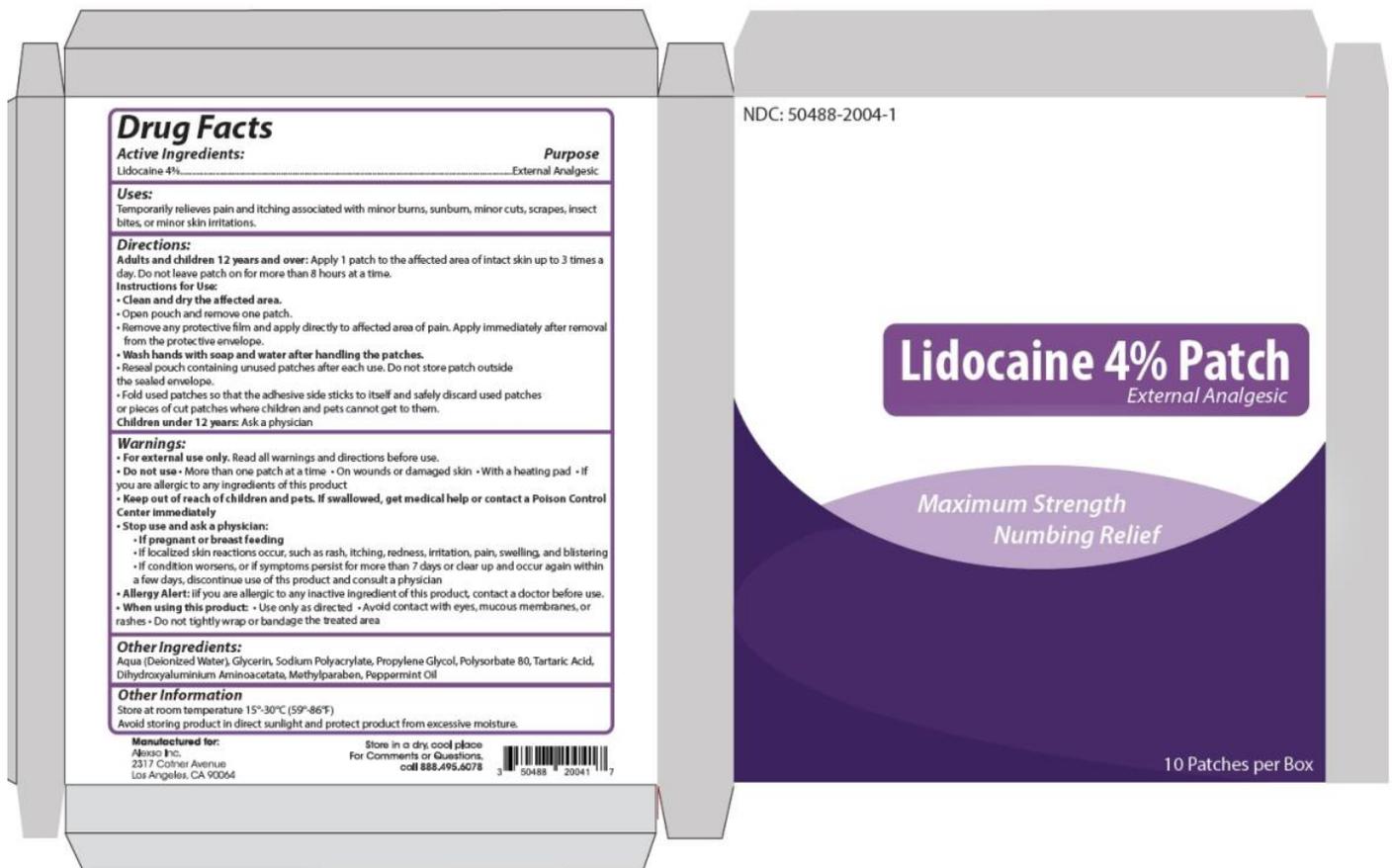
## PRINCIPAL DISPLAY PANEL

### Lidocaine 4% Patch

NDC 50488-2004-1

### 10 Patches per Box

Alexso, Inc



## LIDOCAINE

lidocaine patch

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:50488-2004

**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TARTARIC ACID (UNII: W4888I119H)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50488-2004-1	10 in 1 CARTON	01/15/2020	
1		100 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 NOT FINAL	part348	01/15/2020	

**Labeler** - Alexso, Inc (963338061)

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Alexso, Inc