

**AUVON LIDOCAINE MENTHOL PAIN RELIEF- lidocaine and menthol patch  
SHENZHEN YUWEN E-COMMERCE CO., LTD.**

*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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**83391-001**

**AUVON LIDOCAINE MENTHOL Pain Relief Patch**

**Drug Facts**

**Active ingredients**

Lidocaine 4%

Menthol 1%

**Purposes**

Topical anesthetic

Topical analgesic

**Use**

for the temporary pain relief

**Warnings**

**For external use only**

**Do not use**

- If you are allergic to the listed ingredients
- If you are pregnant or breast feeding
- If you are under 12 years of age
- On wounds, cuts, damaged/broken/irritated skin
- On eyes or mucous membranes
- With heating pads/devices or wrap with a bandage
- With other topical analgesics
- If the package arrives damaged or opened.

**When using this product**

■ Use only as directed

■ Read and follow all directions and warnings on this label

- avoid contact with the eyes and mucous membranes
- rare cases of serious burns have been reported with products of this type
- a transient burning sensation may occur upon application but generally disappears in several days
- dispose of used patch in manner that always keeps product away from children and 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**

You are experiencing pain, swelling or blistering

Redness is present or irritation develops

Symptoms persist for more than 7 days or clear up and occur again within a few days

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

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

### **Directions**

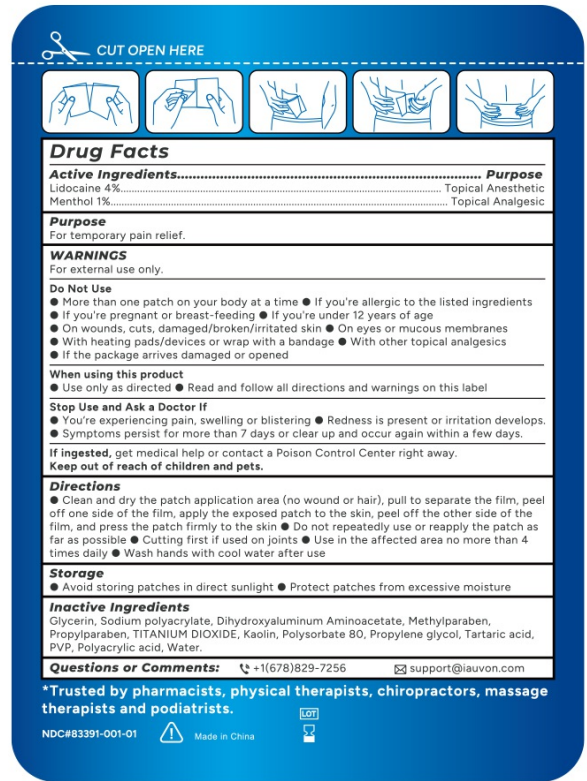
- Clean and dry the patch application area (no wound or hair), pull to separate the film, peel off one side of the film, apply the exposed patch to the skin, peel off the other side of the film, and press the patch firmly to the skin.
- Do not repeatedly use or repeatedly reapply the patch as far as possible
- Cut first if used on joints
- Use in the affected area no more than 4 times daily
- Wash hands with cool water after use

### **Storage**

- Avoid storing patches in direct sunlight
- Protect patches from excessive moisture

### **Inactive ingredients**

Glycerin, sodium polyacrylate, dihydroxyaluminum aminoacetate, methylparaben, propylparaben, polyacrylic acid, Kaolin, polysorbate 80, propylene glycol, tartaric acid, PVP, titanium dioxide, water



## AUVON LIDOCAINE MENTHOL PAIN RELIEF

lidocaine and menthol patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83391-001
<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	370 mg
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JNI2J)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS</b> (UNII: 1K713C615K)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	

<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>POLYACRYLIC ACID (250000 MW)</b> (UNII: 9G2MAD7J6W)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83391-001-01	1 in 1 CARTON; Type 0: Not a Combination Product	04/12/2023	
2	NDC:83391-001-02	8 in 1 CARTON; Type 0: Not a Combination Product	04/12/2023	
3	NDC:83391-001-03	30 in 1 CARTON; Type 0: Not a Combination Product	04/12/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/12/2023	

**Labeler** - SHENZHEN YUWEN E-COMMERCE CO., LTD. (544559614)

**Registrant** - SHENZHEN YUWEN E-COMMERCE CO., LTD. (544559614)

### Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co., Ltd.,		529128763	manufacture(83391-001)

Revised: 7/2023

SHENZHEN YUWEN E-COMMERCE CO., LTD.