LIDOCAINE 4% PLUS MENTHOL 1% - lidocaine, menthol patch
Icure Pharmaceutical Inc, Wanju Factory

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.

Drug Facts

lidocaine, menthol

Methylparaben, Propylparaben, Sodium Polyacrylate, Polyacrylic Acid 20% Solution, Gelatin, Carboxymethyl Cellulose, Titanium Oxide, Kaolin, Dihydroxyaluminium Aminoacetate, Concentrated Glycerin, D-Sorbitol Solution, Urea, Polysorbate 80, Sorbitan Oleate, Disodium Edetate Hydrate, Tartaric Acid, Propylene Glycol, Purified Water

Temporary relief of minor pain

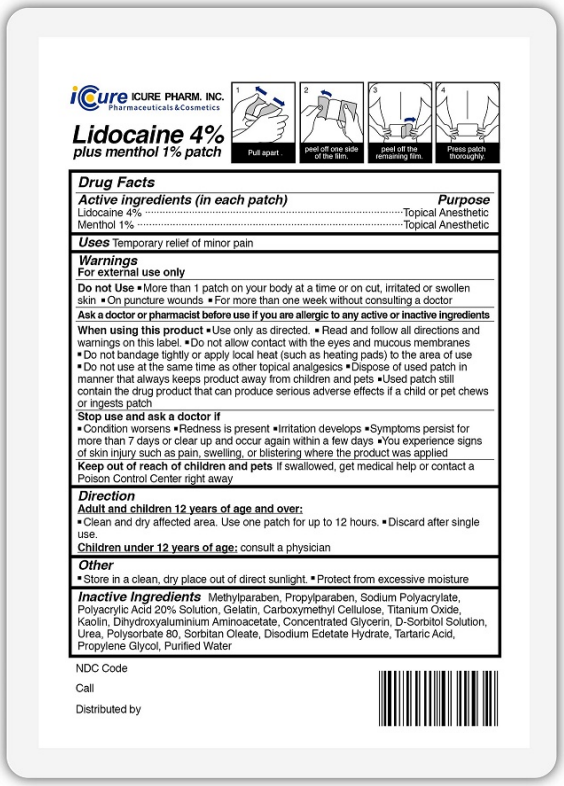
keep out of reach of the children

Use only as directed. Read and follow all directions and warnings on this label.
Do not allow contact with the eyes and mucous membranes
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 and pets
Used patch still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests patch

- Warnings
For external use only.
Ask a doctor or pharmacist before use if you are allergic to any active or inactive ingredients.

- 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

for external use only



LIDOCAINE 4% PLUS MENTHOL 1%

lidocaine, menthol patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73279-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73279-0001-2	5 in 1 POUCH	08/31/2019	
1	NDC:73279-0001-1	6 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	08/31/2019	

Labeler - Icure Pharmaceutical Inc, Wanju Factory (695687612)

Registrant - Icure Pharmaceutical Inc, Wanju Factory (695687612)

Establishment

Name	Address	ID/FEI	Business Operations
Icure Pharmaceutical Inc, Wanju Factory		695687612	manufacture(73279-0001) , label(73279-0001)

Revised: 9/2019 Icure Pharmaceutical Inc, Wanju Factory