TOPLAST PAIN RELIEF LIDOCAINE 4PERCENT- lidocaine 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

ACTIVE INGREDIENTS

Lidocaine 4%

INACTIVE INGREDIENTS

Glycerin, Propylene Glycol, D-Sorbitol Solution, Sodium Polyacrylate, Polyacrylic Acid, Urea, Gelatin, Carboxymethylcellulose Sodium, Kaolin, Castor Oil, Polyvinyl Alcohol, Titanium Oxide, Tartaric Acid, Methylparaben, Dihydroxyaluminum Aminoacetate, Disodium Edetate Hydrate, Polysorbate 80, Propylparaben, Sorbitan Oleate, Water

PURPOSE

Topical Anesthetic

WARNINGS

For external use only

Do not use

■ More than 1 patch on your body at a time ■ On the cut, irritated, swollen or puncture wounds ■ For more than one week without consulting a doctor

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Ask a doctor or pharmacist before use if you are allergic to any active or inactive ingredients

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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 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 ■ Make sure to dispose the used patch away from children and pets, as used ones still contain the drug that can cause serious adverse effects on them if they chew or ingest the patch

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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

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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

Uses

For temporary relief of minor pain

Directions

Adult and children 12 years of age and over :
■ Clean and dry affected area ■ Peel film from patch and apply to the skin (see illustration) ■ Use 1 patch for up to 12 hours
Children under 12 years of age : Consult a physician

Other Information

■ Store at room temperature 68° to 77°F (20° to 25°C) ■ Store in a clean, dry place out of direct sunlight ■ Protect from excessive moisture

Questions or Comments

■ Visit us at : icure.co.kr/en ■ Contact us : icurepharm@icure.co.kr

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

TOPLAST PAIN RELIEF LIDOCAINE 4PERCENT

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73279-0005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Lidocaine (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	Lidocaine	240 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
Urea (UNII: 8W8T17847W)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
Gelatin (UNII: 2G86QN327L)	
Kaolin (UNII: 24H4NWX5CO)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Tartaric Acid (UNII: W4888I119H)	
Methylparaben (UNII: A2I8C7HI9T)	
Dihydroxyaluminum Aminoacetate (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Propylparaben (UNII: Z8IX2SC1OH)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73279-0005-2	5 in 1 CARTON	07/01/2020	
1	NDC:73279-0005-1	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 not final	part348	07/01/2020	

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(73279-0005)