ODYNIA-U - lidocaine, capsicum patch
Ursh Pharmaceutical 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.

Drug Facts

Active Ingredient

Lidocaine 4 %

Capsicum 0.03 %

Purpose

Topical Analgesic

External Analgesic

Uses temporarily relieves minor aches and pains associated with: -arthritis -simple backache --bursitis --tendonitis

--muscle strains --sprains --bruises --cramps

Warnings

For external use only

When using this product -use only as directed -do not bandage tightly or use with a heating pad

-avoid contact with eyes and mucus membranes -do not apply to wounds or damaged, broken or irritated skin

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

If pregnant or breast feeding, ask a health professional before use

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

adults and children over 12 years:

-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

-wear one Icy Hot Patch up to 8 hours

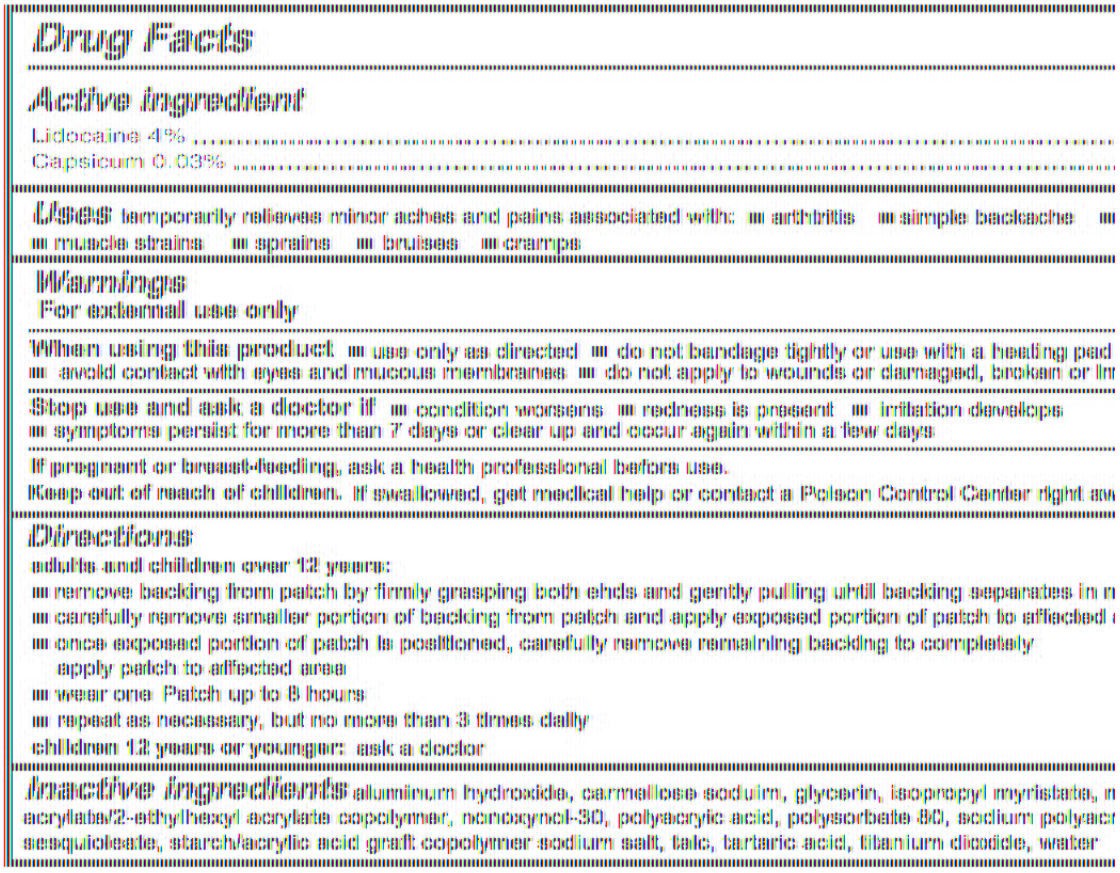
-repeat as necessary, but no more than 3 times daily

children under 12 years or younger: ask a doctor

Inactive ingredients aluminum hydroxide, carmellose sodium, glycerin, isopropyl myristate, methyl

acrylate / 2 -ethylhexyl acrylate copolymer, nonoxynol-30, polyacryic acid, polysorbate 80, sodium polyacrylate, sorbitan

sesquioleate, starch / acrylic acid graft copolymer sodium salt, talc, tartaric acid, titanium dioxide, water



ODYNIA-U

lidocaine, capsicum patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69647-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g
CAPSICUM (UNII: 00UK7646FG) (CAPSICUM - UNII:00UK7646FG)	CAPSICUM	.03 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL ACRYLATE (UNII: WC487PR91H)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
ACRYLIC ACID (UNII: J94PBK7X8S)	
SODIUM (UNII: 9NEZ333N27)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69647-003-01	15 in 1 BOX		
1		10 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	03/12/2015	

Labeler - Ursh Pharmaceutical Inc. (079715344)

Revised: 5/2015 Ursh Pharmaceutical Inc.