

**LIDOCAINE DRY PATCH PLUS MENTHOL- lidocaine 4% and menthol 1% patch
SAFREL PHARMACEUTICALS, LLC**

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.

LIDOCAINE DRY PATCH PLUS MENTHOL - lidocaine 4% and menthol 1% patch

Active ingredient

Lidocaine 4%

Menthol 1%

Purpose

Topical Anesthetic

Uses

Temporarily relieves minor pain associated with: arthritis, simple backache, bursitis, tendonitis, muscle strains, sprains & bruises.

Warning

For external use only

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

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
- 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 or 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

- 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

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.

Directions:

Adults and children over 12 years:

- clean and dry affected area
- 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
- use 1 patch for up to 12 hours

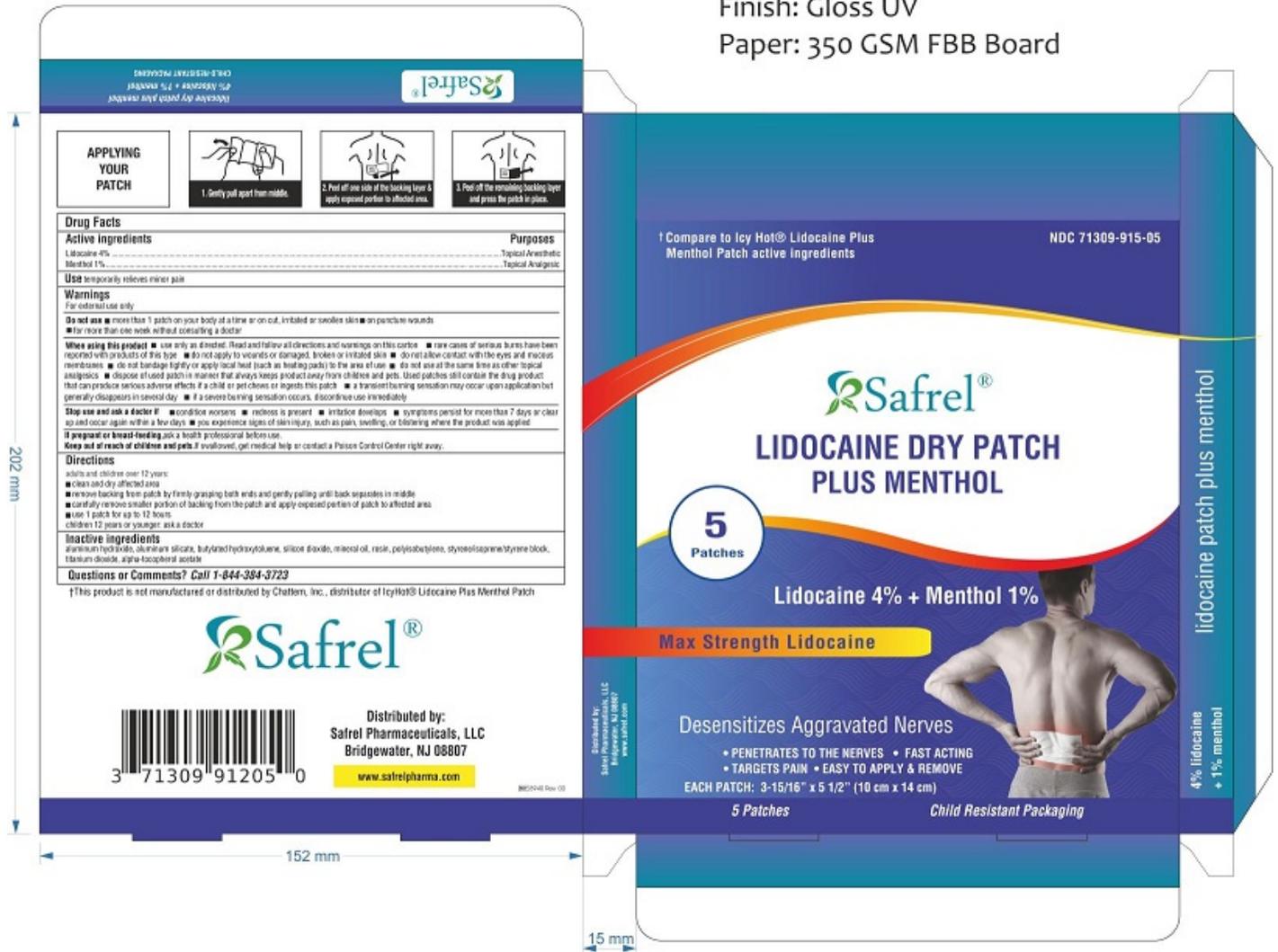
children 12 years or younger: ask a doctor

Inactive Ingredients

kaolin, polysorbate 80, polyacrylic acid, silicon dioxide, sodium polyacrylate, titanium dioxide

Package / Principle Label

CMYK Process Colour
 Finish: Gloss UV
 Paper: 350 GSM FBB Board



Package / Inner Pouch



OPTION 2

LIDOCAINE DRY PATCH PLUS MENTHOL

lidocaine 4% and menthol 1% patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-915
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg

Inactive Ingredients

Ingredient Name	Strength
KAOLIN (UNII: 24H4NWX5CO)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	
Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-915-05	5 in 1 BOX	03/15/2022	
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 final	part346	03/15/2022	

Labeler - SAFREL PHARMACEUTICALS, LLC (080566287)

Registrant - SAFREL PHARMACEUTICALS, LLC (080566287)

Establishment

Name	Address	ID/FEI	Business Operations
DR. SABHARWAL'S WOUND CARE		862184668	manufacture(71309-915)

Revised: 3/2022

SAFREL PHARMACEUTICALS, LLC