PAIN RELIEF 4% LIDOCAINE DRY PATCH- lidocaine 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.

Pain Relief 4% Lidocaine Dry Patch

Active ingredient

Lidocaine 4%

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:

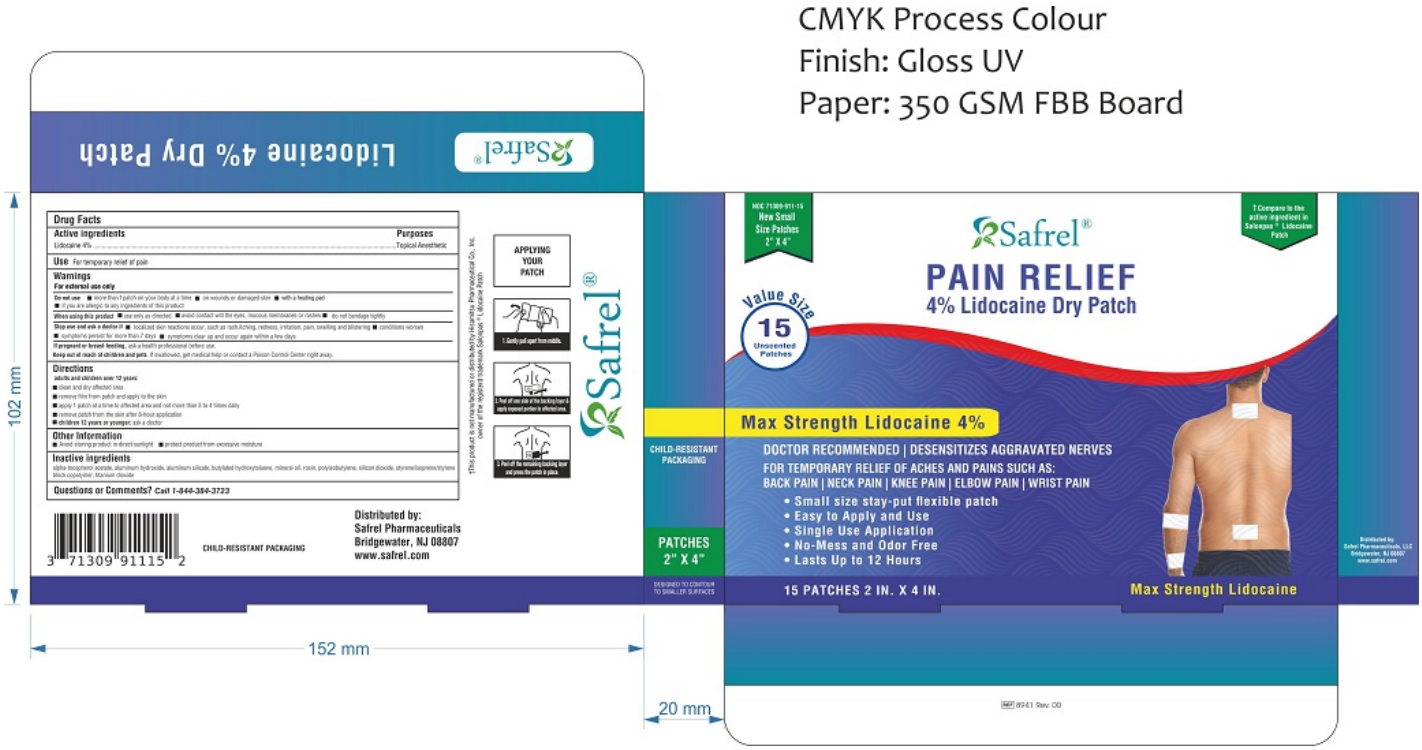
- clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully 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

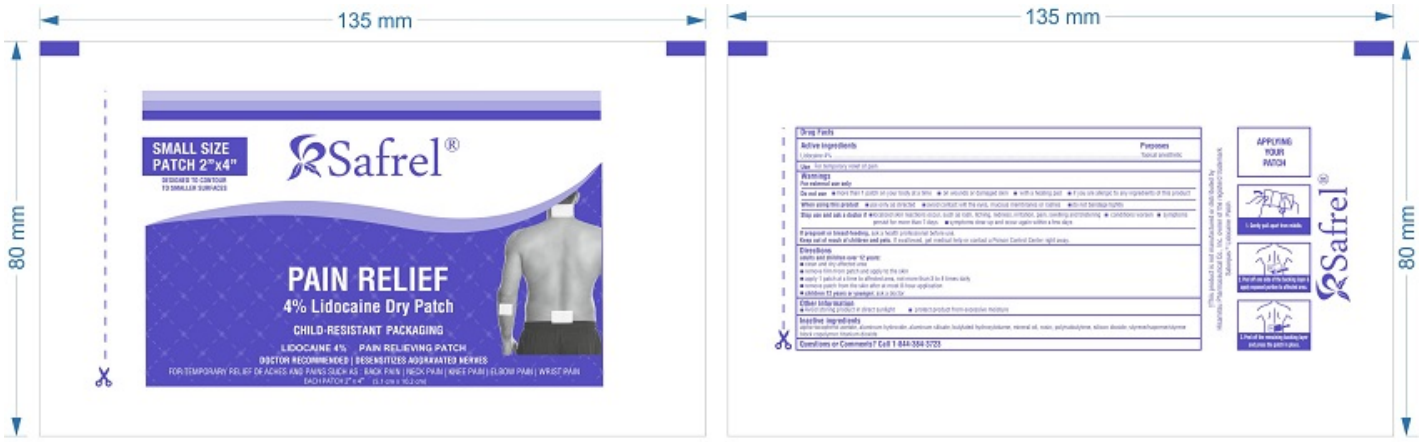
Inactive Ingredients

aluminum silicate, butylated hydroxytoluene, silicon dioxide, mineral oil, rosin, polyisobutylene (1000 mw), styrene/isoprene/styrene block copolymer, titanium dioxide, .alpha.-tocopherol acetate

Package / Principle Label



Package / Inner Pouch



OPTION 2

PAIN RELIEF 4% LIDOCAINE DRY PATCH

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71309-911
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM SILICATE (UNII: T1FAD4SS2M)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MINERAL OIL (UNII: T5L8T28FGP)	
ROSIN (UNII: 88S87KL877)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER (UNII: K7S96QM8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

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:71309-911-15	15 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	part348	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(71309-911)

Revised: 3/2022 SAFREL PHARMACEUTICALS, LLC