NIRAVI 24 HOURS LIDOCAINE 4 % PATCH- lidocaine patch Sparsha Pharma USA, 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.

Niravi 24 Hours Lidocaine 4% Patch

Active Ingredient

Lidocaine 4%

Purpose

Topical anesthetic

Use

For the temporary relief of minor pain.

Warnings

For External Use Only

Do not use

- If you are allergic to any active or inactive ingredients of this product
- On wounds or damaged, irritated or sensitive skin
- With any other topical anesthetic
- For more than one week without consulting a doctor
- With a heating pad
- If pouch is damaged or opened.

When using this product

- Do not allow contact with the eyes
- Use only as directed
- Read and follow all directions and warnings on this package
- Do not bandage tightly or apply local heat to the area of use
- Do not reuse patch
- Keep this product away from pets and children. Used patches still contains the drug product that can produce serious adverse effect if child or pet chews or ingest this patch.

Stop use and ask a doctor if

- Condition worsens
- Symptoms persist for more than seven days or clear up and occur again within a few days
- Localized skin reactions occur such as rash, pain, itching, redness, irritation, 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 chewed or swallowed, get medical help or contact a Poison Control Center right away (800-222-1222).

Directions

Adults and children 12 years of age and over: Clean and dry affected area. Apply immediately upon removal from pouch. Peel off the first liner and apply exposed patch to affected area. Peel off second liner while applying the rest of patch. Remove patch after 24 hours. Do not expose area to heat.

Children under 12 years of age: Consult a doctor.

Inactive Ingredients

Alicyclic hydrocarbon resin, mineral oil, polyester film, silicon-coated polyester film and styrene isoprene styrene block copolymer.

Other information

.Store in a clean, dry place away from direct sunlight. Store in original unopened pouch. protected from moisture.

Questions?

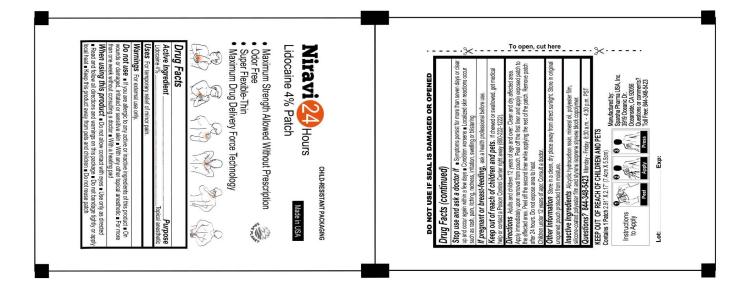
Customer Care Helpline 844-348-5423 Monday- Friday 8:30 a.m - 4:30 p.m PST

PACKAGE LABEL

Carton Label NDC 73638-901-01







NIRAVI 24 HOURS LIDOCAINE 4 % PATCH

lidocaine patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73638-901
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	

Inactive Ingredients			
Ingredient Name	Strength		
MINERAL OIL (UNII: T5L8T28FGP)			
HYDROGENATED C6-20 POLYOLEFIN (100 CST) (UNII: 39EYQ1W9RB)			
STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER (STYRENE/ISOPRENE 15/85) (UNII: 1SSZ6HXE7P)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73638-901- 01	6 in 1 CARTON	06/30/2021	
1		1 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	06/30/2021	

Labeler - Sparsha Pharma USA, Inc. (079365856)

Registrant - Sparsha Pharma USA, Inc. (079365856)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sparsha Pharma USA, Inc.		079365856	manufacture(73638-901)	

Revised: 1/2023 Sparsha Pharma USA, Inc.