

**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**



Unvarnished Area

Manufactured by:  
Sparsa Pharma USA, Inc.  
3919 Oceanic Dr.  
Oceanside, CA 92056  
Call for more information?  
Toll Free: 844-348-5423

VIA BRUCOLINE 7/8 POUCHES

**Drug Facts**

**Active Ingredient** ..... **Purpose**  
Lidocaine 4% ..... Topical anesthetic

**Use** For 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 a child or pet chews or ingests 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, silicone-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.



Unvarnished Area

Unvarnished Area

8 60003 69920 7

**Niravi 24 Hours** Lidocaine 4% Patch

Customer Care Help Line 844-348-5423 Monday - Friday 8:30 a.m. - 4:30 p.m. PST  
**KEEP OUT OF REACH OF CHILDREN AND PETS**

Read directions and warning before use

Consistent Drug Delivery for up to 24 hours

- Maximum Strength Allowed Without Prescription
- Odor Free
- Super Flexible-Thin
- Maximum Drug Delivery Force Technology

**Niravi 24 Hours** Lidocaine 4% Patch

**SPARSHA USA**

Made in USA

**6** Patches (35mm x 74mm)  
Patch Size 2.17" x 2.91"

CHILD-RESISTANT PACKAGING NDC 79368-901-01

**Niravi 24 Hours** Lidocaine 4% Patch

**Niravi 24 Hours**  
Lidocaine 4% Patch

Pouch Label

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active Ingredient</b>	Lidocaine 4% Topical anesthetic
<b>Uses</b> For temporary relief of minor pain.	
<b>Warnings</b> For external use only.	
<b>Do not use</b> ■ 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.	
<b>When using this product</b> ■ Do not allow contact with eyes. ■ Use only as directed.	
<b>Read and follow all directions and warnings on this package</b> ■ Do not change light or apply local heat. ■ Keep this product away from pets and children. ■ Do not reuse patch.	



- Maximum Strength Allowed Without Prescription
- Odor Free
- Super Flexible-Thin
- Maximum Drug Delivery Force Technology



**Niravi** 24 Hours  
Lidocaine 4% Patch

Made in USA

CHILD-RESISTANT PACKAGING

**DO NOT USE IF SEAL IS DAMAGED OR OPENED**

**Drug Facts (continued)**

**Stop use and ask a doctor if** ■ Symptoms persist for more than seven days or clear up and occur again within a few days ■ Condition worsens ■ Localized skin reactions occur such as rash, pain, itching, redness, irritation, swelling or blistering

**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 the affected area. Peel off the second liner while applying the rest of the patch. Remove patch after 24 hours. Do not expose area to heat.

**Other Information** Store in a clean, dry place away from direct sunlight. Store in original unopened patch protected from moisture.

**Inactive Ingredients** Alkylic hydrocarbon resin, mineral oil, polyester film, silicone/acrylic polymer film and styrene styrene styrene block copolymer.

**Questions?** 844-348-5423 Monday - Friday, 8:30 a.m. - 4:30 p.m. PST

**KEEP OUT OF REACH OF CHILDREN AND PETS**  
Contains 1 Patch 2.91" X 2.17" (7.4cm X 5.5cm)

Manufactured by:  
Spanna Pharma USA, Inc.  
3819 Oceanic Dr.  
Oceanside, CA 92056  
Call Center: 844-348-5423  
Toll Free: 844-348-5423

Instructions to Apply:

Lot: ..... Exp: .....

# NIRAVI 24 HOURS LIDOCAINE 4 % PATCH

lidocaine patch

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73638-901
<b>Route of Administration</b>	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.