**LOXYINE- lidocaine patch**
**Sj Incorporation Ltd**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

---

**Loxyine**
**Maximum Strength**
**Lidocaine**
**Pain Relieving Patch**

## Active ingredient

Lidocaine 4.0%

## Purpose

Topical anesthetic

## Uses

Temporarily relieves minor pain.

## Warnings

**For external use only**

**Do not use**

- more than one patch on your body at a time
- On cut, irritated or swollen skin
- On puncture wounds
- For more than one week without consulting a doctor
- If you are allergic to any active or inactive ingredients
- If pouch is damaged or opened.

**When using this product**

- use only as directed
- Read and follow all directions and warning on this pack
- Do not allow contact with the eyes
- Do not use at the same time as other topical analgesics
- Do not bandage only tightly or apply local heat (such as heating pads) to the area of use
- Do not microwave
- Dispose of used patch in manner that always keeps product away from children and 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 or skin injury, such as pain, swelling or blistering where the product was applied.

**If pregnant or breast-feeding,**

ask a healthcare professional before use.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center (1800-222-1222) right away.

**Directions**

**Adults and children 12 years of age and over:** Clean and dry affected area. Remove film from patch (see illustration). Apply sticky side of patch to affected area. Use one path for up to 12 hours. Discard patch after single use.

**Children under 12 years of age:** Consult a physician.

**Other information**

Store in a clean, dry place outside of direct sunlight. Protect from excessive moisture.

**Inactive ingredients**

aluminum glycinate, glycerin, kaolin, methylparaben, polyacrylic acid, polysorbate 80, propylene glycol, propylparaben, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, water.

**Questions or comments?**

Toll free **1-800-587-4041**

**Principal Display Panel**

NDC 83658-011-01

# Loxyine

## MAXIMUM STRENGTH

## LIDOCAINE PAIN RELIEVING PATCH

Lidocaine 4% / Topical Anesthetic

*Compare to Salonpas Maximum Strength Lidocaine Patch active ingredient**

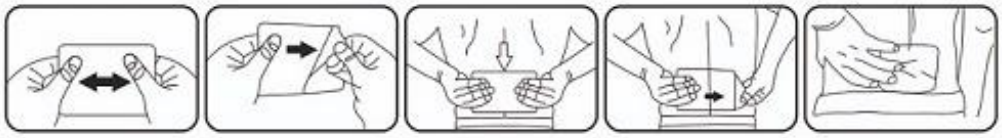
*Temporarily* ***relieves pain***

- ☑ Stay-put flexible patch
- ☑ Easy to apply and remove
- ☑ No-mess, single-use application
- ☑ Odor Free

**1 PATCH** LASTS UP TO 12 HOURS

*3.93 in x 5.5 in (10 cm x 14 cm)*

OPEN HERE



## Drug Facts

**Active Ingredients** — **Purpose**

Lidocaine 4.0% ..... Topical anesthetic

**Uses** Temporarily relieves minor pain.

## Warnings

**For external use only**

**Do not use** • More than one patch on your body at a time • On cut, irritated or swollen skin • On puncture wounds • For more than one week without consulting a doctor • If you are allergic to any active or inactive ingredients • If pouch is damaged or opened.

**When using this product** • Use on as directed • Read and follow all directions and warnings on this pack • Do not allow contact with the eyes • Do not use at the same time as other topical analgesics • Do not bandage only tightly or apply local heat (such as heating pads) to the area of use • Do not microwave • Dispose of used patch in manner that always keeps product away from children and 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 or skin injury, such as pain, swelling or blistering where the product was applied.

**If pregnant or breast feeding** ask a healthcare professional before use.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center (1800-222-1222) right way.

**Directions** • Adults and children over 12 years: Clean and dry affected area. Remove film from patch (see illustration). Apply sticky side of patch to affected area. Use one patch for up to 12 hours. Discard patch after single use.

• **Children 12 years of age or younger:** Consult a physician.

**Other Information**

Store in a clean, dry place outside of direct sunlight. Protect from excessive moisture.

**Inactive Ingredients**

aluminum glycinate, glycerin, kaolin, methylparben, polyacrylic acid, polysorbate 80, propylene glycol, propylparaben, PVP, sodium polyacrylate, tartaric acid, titanium dioxide, water

**Questions of Comments** Call 1800-587-4041

Satisfaction guaranteed - Or we'll replace it or give you money back. For questions or comments or to report an undesired reaction or side effect, please call 1800-587-4041

**DISTRIBUTED BY:**
SJ Incorporation Ltd.
Illinois, USA

**Not For Individual Retail Sale.**

MULTI-LAYER POUCH

# LOXYINE

lidocaine patch

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:83658-011 |
| **Route of Administration** | TOPICAL, PERCUTANEOUS, TRANSDERMAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **LIDOCAINE** (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 4 mg in 100 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ALUMINIUM TRIGLYCINATE** (UNII: 5TLG1CL557) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **KAOLIN** (UNII: 24H4NWX5CO) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **POLYACRYLIC ACID (8000 MW)** (UNII: 73861X4K5F) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **SODIUM POLYACRYLATE (8000 MW)** (UNII: 285CYO341L) | |
| **TARTARIC ACID** (UNII: W4888I119H) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **WATER** (UNII: 059QF0KO0R) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:83658-011-01 | 1 mg in 1 POUCH; Type 0: Not a Combination Product | 11/20/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 11/20/2023 | |

## Labeler - Sj Incorporation Ltd (119051828)

## Registrant - Sj Incorporation Ltd (119051828)

Revised: 11/2023 Sj Incorporation Ltd