

TRICEPTIN- lidocaine / menthol / methyl salicylate patch
SOLA Pharmaceuticals

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.

Triceptin Patch

Active ingredient (in each packet)

Lidocaine 4%

Purpose

Topical anesthetic

Active ingredient (in each packet)

Menthol 1%

Purpose

Topical analgesic

Active ingredient (in each packet)

Methyl salicylate 2%

Purpose

Topical analgesic

Use

Temporarily relieves mild to moderate aches and pains of muscles and joints associated with:

- Muscle soreness
- strains
- sprains
- arthritis
- simple backache
- muscle stiffness
- bruises

Warnings

For external use only

Stomach bleeding warning: This product contains a NSAID, which may cause stomach bleeding. The chance is small, but higher if you

- are aged 60 or older
- have had stomach ulcers or bleeding problems
- take other drugs containing an NSAID (Aspirin, ibuprofen, Naproxen, or others)
- take a blood thinning (anticoagulant) or steroidal drug
- have three or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

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 warnings on this carton
- Do not allow contact with the eyes
- Do not use at the same time as other topical analgesics
- Do not bandage tightly or apply local heat (such as heating pads) to the area of use
- Do no 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 consult 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
- Stomach pain or upset gets worst or lasts
- You feel faint, vomit blood, or have bloody or black stools (these are signs or stomach bleeding).

If pregnant or breastfeeding

ask a healthcare 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, or children over the age of 12: Clean and dry affected area. Carefully remove backing from patch starting at a corner. Apply sticky side of patch to affected area and leave in place for 8 to 12 hours. If pain lasts after using the first patch, a second patch may be applied for up to another 8 to 12 hours. Only use one patch at a time. do not use more than 2 patches per day. Wash hands with soap and water after applying or removing patch. reseal pouch containing unused patches immediately after each use. Children under 12 years of age: Do not use.

Other information

Store at 68°F-77°F (20°C-25°C).

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

Some individuals may not experience pain relief until several minutes or hours after applying the patch.

Inactive ingredients

Arnica montana flower extract, Dihydroxyaluminum aminoacetate, Edetate disodium, Glycerin, Hydroxyacetophenone, Kaolin, L-Tartaric acid, Mineral oil, Polyacrylic acid, Propylene glycol, Polysorbate 80, PVP, Sodium polyacrylate, Titanium dioxide, Water.

Questions or comments?

866-747-7365

Manufactured for:

SOLA PHARMACEUTICALS LLC

Baton Rouge, LA 70810

www.solameds.us

Made in China

Triceptin

Topical Pain Patch

for temporary pain relief

NDC 70512-017-15

Qty: 15 patches

(5 per Resealable Pouch) x 3



TRICEPTIN

lidocaine / menthol / methyl salicylate patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70512-017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	20 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength

ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
WATER (UNII: 059QF0KO0R)
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GLYCERIN (UNII: PDC6A3C0OX)
MINERAL OIL (UNII: T5L8T28FGP)
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)
POVIDONE K90 (UNII: RDH86HJV5Z)
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)
KAOLIN (UNII: 24H4NWX5CO)
TARTARIC ACID (UNII: W4888I119H)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)

Product Characteristics

Color		Score	
Shape	RECTANGLE	Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70512-017-15	3 in 1 BOX	12/05/2022	
1		5 g in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/05/2022	

Labeler - SOLA Pharmaceuticals (080121345)