SALICOR- triethanolamine salicylate patch
Clinic Pharma

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.

SALICOR (triethanolamine salicylate patch)

DESCRIPTION

Salicor™ is an external analgesic product containing 10% triethanolamine salicylate as the active ingredient. Triethanolamine salicylate is an organic compound formed between triethanolamine and salicylic acid, where triethanolamine neutralizes the acidity of salicylic acid. This external analgesic is designed for temporary relief of minor pain associated with arthritis, simple backache, muscle strains, sprains, and bruises. Unlike other external analgesics, triethanolamine salicylate has no distinct odor, which improves patient acceptability.

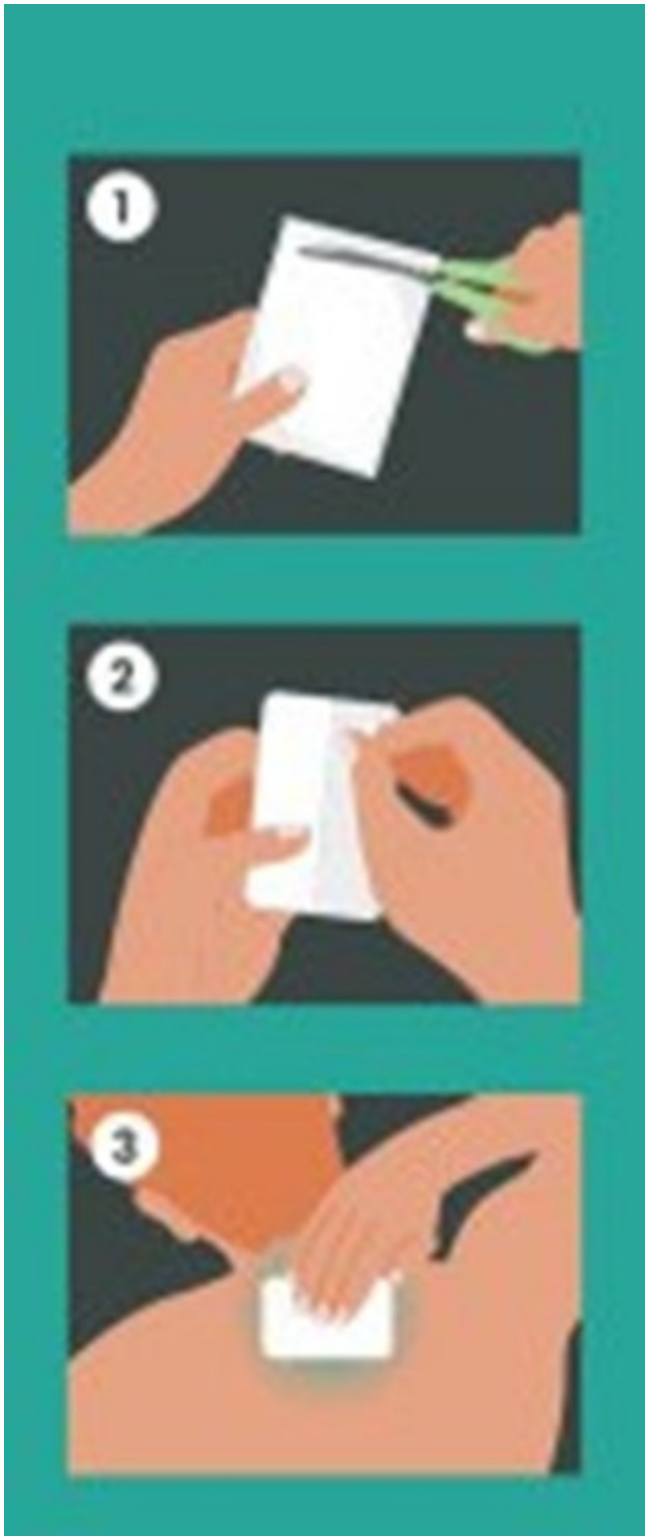
HOW SUPPLIED

Salicor™ is available as the following:
1 carton, 15 systems
NDC 83881-501-15

DOSAGE AND ADMINISTRATION

For adults 18 years and older:
• Clean and dry the affected area
• Locate the tear notch on the edge of the pouch. Tear open at the notch or carefully cut open the pouch with scissors, taking care not to cut the system inside
• Remove the transparent release liner before applying Salicor™ to the skin
• Apply one Salicor™ to the affected area of pain and leave it in place for 8 to 12 hours
• Apply only one Salicor™ at a time
• If pain persists, the used Salicor™ may be replaced with a new one for up to 8 to 12 more hours
• Always remove and properly dispose of the used Salicor™ before applying a new one
• Salicor™ may be cut into smaller sizes with scissors prior to removing the release liner
• Safely discard the used Salicor™ (whole or cut pieces) where children and pets cannot access it
• Wash hands with soap and water after applying or removing Salicor™

Visual Guide provided below:



These highlights do not include all the information needed to use Salicor™ safely and effectively. See full prescribing information for Salicor™

STORAGE AND HANDLING

Avoid contact with the eyes. Keep away from excessive heat and direct sunlight.
Salicor™ should be kept out of reach of children.
Store at 20° to 25°C (68° to 77°F).
[See USP Controlled Room Temperature]

Pharmacodynamics

Triethanolamine salicylate is an external analgesic that functions by inhibiting cyclooxygenase (COX) enzymes, which are involved in the production of pro-inflammatory factors such as prostaglandins and thromboxanes. These enzymes play a crucial role in generating pain and inflammation in conditions like arthritis, muscle strains, and sprains. While salicylates, such as aspirin, are known to inhibit COX enzymes, the specific mechanism of triethanolamine salicylate in topical applications may differ slightly. It is generally believed to act similarly to topical NSAIDs, reducing inflammation and pain locally. However, the evidence regarding its selectivity towards COX-2 enzymes is less clear.

Drugs That May Cause Methemoglobinemia When Used with Salicor™

Patients who are administered local anesthetics are at increased risk of developing methemoglobinemia when concurrently exposed to the following drugs, which could include other local anesthetics:

Examples of Drugs Associated with Methemoglobinemia

Class: Nitrates/Nitrites: Local anesthetics: Antineoplastic agents: Antibiotics: Antimalarials: Anticonvulsants: Other drugs: Examples: nitric oxide, nitroglycerin, nitroprusside, nitrous oxide articaine, benzocaine, bupivacaine, lidocaine, mepivacaine, prilocaine, procaine, ropivacaine, tetracaine cyclophosphamide, flutamide, hydroxyurea, ifosfamide, rasburicase dapsone, nitrofurantoin, para-aminosalicylic acid, sulfonamides chloroquine, primaquine phenobarbital, phenytoin, sodium valproate acetaminophen, metoclopramide, quinine, sulfasalazine carcinogenesis, mutagenesis

Pharmacokinetics

Absorption

Following external administration of Salicor™ to healthy volunteers, no detectable levels of salicylic acid were found in the serum, indicating low systemic absorption. This minimal absorption is advantageous as it reduces the risk of systemic side effects commonly associated with oral salicylates. Studies have shown that urinary recovery of total salicylate during the first 24 hours after external application was only 6.9 mg, which represents approximately 1.4% of the total dose applied.

Distribution

Triethanolamine salicylate is transported and distributed within cells and tissues through various mechanisms. Studies in canines and humans have shown that transdermal absorption of salicylate from triethanolamine salicylate preparations applied to skin is consistent and reproducible, with measurable tissue salicylate levels at the application site. The distribution appears to be concentration-dependent, with tissue salicylate levels directly proportional to the concentrations of the active ingredient in the formulation up to the 10% preparation.

Metabolism

While specific metabolism data for externally applied Salicor™ is limited due to its low systemic absorption, the small amount that does enter the systemic circulation is likely metabolized similarly to other salicylates. The primary metabolic pathways include:
1. Conjugation with glycine to form salicyluric acid (approximately 75%).
2. Conjugation with glucuronic acid to produce salicyl acyl and phenolic glucuronides (about 15%).
3. Oxidation to gentisic acid and other hydroxylated derivatives (minor pathway).
Free, unmodified salicylate accounts for 10–30% of excreted metabolites, depending on dosage and individual factors like urinary pH. Metabolism primarily occurs in the liver, with some possible local metabolism in skin tissues.

Excretion
Triethanolamine salicylate is primarily excreted through the urine after metabolism. Following external application of a 10% formulation, approximately 1.4% of the total dose is recovered in the urine as salicylate within the first 24 hours, indicating low systemic absorption.

INDICATION AND USAGE

Salicor™ is indicated for the temporary relief of minor aches and pains of muscles and joints associated with: arthritis, simple backache, muscle strains and sprains, bruises, bursitis, and dysmenorrhea.
Salicor™ provides a localized analgesic effect directly at the site of pain, offering convenience and sustained relief compared to cream formulations.

PRECAUTIONS

General

If irritation or a burning sensation occurs during application, wash the product off your skin and do not reapply until the irritation subsides.
When Salicor™ is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

Stop use and ask a doctor if
• Condition worsens
• Symptoms persist for more than 7 days, or symptoms return within a few days after discontinuing use
• Redness is present
• Irritation develops

Hepatic Disease
Patients with severe hepatic disease are at greater risk of developing toxic blood concentrations of triethanolamine salicylate because of their inability to metabolize triethanolamine salicylate normally.

Allergic Reactions
Although rare, allergic reactions to oral or external triethanolamine salicylate may occur. Seek emergency medical help if you experience hives, difficulty breathing, or swelling of the face, lips, tongue, or throat, as these may indicate a serious allergic reaction.

Non-intact Skin

Although not tested, application to broken or inflamed skin may result in higher blood concentrations of triethanolamine salicylate from increased absorption. Salicor™ is only recommended for use on intact skin.

External Heat Sources

Placement of external heat sources, such as heating pads or electric blankets, over Salicor™ is not recommended, as this has not been evaluated and may increase plasma triethanolamine salicylate levels.

Eye Exposure
Although not studied, contact of Salicor™ with the eyes should be avoided based on the findings of severe eye irritation with the use of similar animal products. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye until sensation returns.

Information for Patients Methemoglobinemia
Inform patients that the use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. Advise patients or caregivers to stop use and seek immediate medical attention if they or someone in their care experiences the following signs or symptoms: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue.

OVERDOSAGE

Salicor™ is intended for external use only. While systemic toxicity is unlikely with proper use, accidental ingestion or excessive application may lead to salicylate toxicity. Symptoms of overdose may include: nausea and vomiting, tinnitus (ringing in the ears), dizziness and confusion, rapid breathing (hyperventilation), sweating, headache, and fever.
In severe cases, overdose may lead to more serious symptoms such as: seizures, hallucinations, respiratory distress, kidney failure, and metabolic acidosis.
If overdose is suspected, discontinue use immediately and seek medical attention. Treatment is supportive and symptomatic. Healthcare professionals may need to monitor fluid and electrolyte balance, correct acid-base disturbances, and manage any complications.

Pregnancy

Before taking NSAIDs, tell your healthcare provider about all of your medical conditions, including if you are pregnant or plan to become pregnant. Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs after about 30 weeks of pregnancy.

Pregnancy Category B.
Salicor™ has not been studied in pregnancy.

Labor and Delivery

Salicor™ has not been studied in labor and delivery.

Lactation

Salicor™ has not been studied in nursing mothers.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Patient Package Insert

NDC 83881-501-15

Salicor™
TRANSDERMAL SYSTEM

Triethanolamine Salicylate 10%

DISPENSED BY PRESCRIPTION

INDICATIONS AND USAGE
Salicor™ is indicated for the temporary relief of minor aches and pains of muscles and joints associated with: arthritis, simple backache, muscle strains and sprains, bruises, bursitis, and dysmenorrhea.

Salicor™ provides a localized analgesic effect directly at the site of pain, offering convenience and sustained relief compared to cream formulations.

DOSAGE AND ADMINISTRATION
For adults 18 years and older:
- Clean and dry the affected area
- Locate the tear notch on the edge of the pouch.

  Tear open at the notch or carefully cut open the pouch with scissors, taking care not to cut the system inside
- Remove the transparent release liner before applying Salicor™ to the skin
- Apply one Salicor™ to the affected area of pain and leave it in place for 8 to 12 hours
- Apply only one Salicor™ at a time
- If pain persists, the used Salicor™ may be replaced with a new one for up to 8 to 12 more hours
- Always remove and properly dispose of the used Salicor™ before applying a new one
- Salicor™ may be cut into smaller sizes with scissors prior to removing the release liner
- Safely discard the used Salicor™ (whole or cut pieces) where children and pets cannot access it
- Wash hands with soap and water after applying or removing Salicor™

If irritation or a burning sensation occurs during application, wash the product off your skin and do not reapply until the irritation subsides.

When Salicor™ is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

CONTRAINDICATIONS
The use of Salicor™ is contraindicated in patients with:
- Known hypersensitivity to salicylates, aspirin, or any components of Salicor™
- History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs
- In the setting of coronary artery bypass graft (CABG) surgery
- Pregnancy at 20 weeks or later

WARNINGS AND PRECAUTIONS
Allergy Alert
If prone to allergic reactions from aspirin or salicylates, consult a doctor before use.

For External Use Only
- Use only as directed
- Do not bandage tightly or use with a heating pad
- Avoid contact with eyes or mucous membranes
- Do not apply to wounds or damaged skin

Risk of Methemoglobinemia
The risk associated with Salicor™ is extremely low to nonexistent. Methemoglobinemia is more commonly linked to the use of local anesthetics like benzocaine, lidocaine, or tetracaine, rather than salicylates such as triethanolamine salicylate. However, while triethanolamine salicylate itself is not typically associated with methemoglobinemia, caution should always be exercised when using any new medication, especially in patients predisposed to this condition, such as those with G6PD deficiency.

Stop use and ask a doctor if
- Condition worsens
- Symptoms persist for more than 7 days, or symptoms return within a few days after discontinuing use
- Redness is present
- Irritation develops

Hepatic Disease
Patients with severe hepatic disease are at greater risk of developing toxic blood concentrations of triethanolamine salicylate because of their inability to metabolize triethanolamine salicylate normally.

Allergic Reactions
Although rare, allergic reactions to oral or external triethanolamine salicylate may occur. Seek emergency medical help if you experience hives, difficulty breathing, or swelling of the face, lips, tongue, or throat, as these may indicate a serious allergic reaction.

Non-intact Skin
Although not tested, application to broken or inflamed skin may result in higher blood concentrations of triethanolamine salicylate from increased absorption. Salicor™ is only recommended for use on intact skin.

External Heat Sources
Placement of external heat sources, such as heating pads or electric blankets, over Salicor™ is not recommended, as this has not been evaluated and may increase plasma triethanolamine salicylate levels.

Eye Exposure
Although not studied, contact of Salicor™ with the eyes should be avoided based on the findings of severe eye irritation with the use of similar animal products. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye until sensation returns.

Information for Patients – Methemoglobinemia
Inform patients that the use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. Advise patients or caregivers to stop use and seek immediate medical attention if they or someone in their care experiences the following signs or symptoms: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue.

Fetal Toxicity
Premature Closure of Fetal Ductus Arteriosus:
Avoid use of NSAIDs, including Salicor™, in pregnant women at about 30 weeks gestation and later. NSAIDs, including Salicor™, increase the risk of premature closure of the fetal ductus arteriosus at approximately this gestational age.

Oligohydramnios/Neonatal Renal Impairment
Use of NSAIDs, including Salicor™, at about 20 weeks gestation or later in pregnancy may cause fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation. Complications of prolonged oligohydramnios may, for example, include limb contractures and delayed lung maturation. In some postmarketing cases of impaired neonatal renal function, invasive procedures such as exchange transfusion or dialysis were required.

If NSAID treatment is necessary between about 20 weeks and 30 weeks gestation, limit Salicor™ use to the lowest effective dose and shortest duration possible. Consider ultrasound monitoring of amniotic fluid if Salicor™ treatment extends beyond 48 hours. Discontinue Salicor™ if oligohydramnios occurs and follow up according to clinical practice.

ADVERSE REACTIONS
Application Site Reactions
While Salicor™ exhibits low skin irritant properties and displays low systemic absorption upon dermal administration, some patients may experience:
- Localized irritation at the application site
- Allergic reactions, particularly in individuals sensitive to salicylates
- In rare cases: blistering, peeling, redness, nausea, vomiting, or tinnitus

Serious Adverse Events (Rare but Require Immediate Medical Attention)
- Serious heart symptoms: fast or pounding heartbeats, fluttering in chest, shortness of breath, sudden dizziness
- Severe headache, confusion, slurred speech, severe weakness, loss of coordination, feeling unsteady
- Severe nervous system reaction: very stiff muscles, high fever, sweating, confusion, fast or uneven heartbeats, tremors, feeling like you might pass out
- Serious eye symptoms: blurred vision, tunnel vision, eye pain or swelling, seeing halos around lights

For more information, talk with your doctor or pharmacist. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
Do not use this product at the same time as other external analgesics. Limited systemic absorption suggests minimal risk of significant drug interactions, but caution should be exercised when using alongside other salicylate-containing products.

Antiarrhythmic Drugs
Salicor™ should be used with caution in patients receiving Class I antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and potentially synergistic.

Local Anesthetics
When Salicor™ is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

Drugs That May Cause Methemoglobinemia When Used with Salicor™
Patients who are administered local anesthetics are at increased risk of developing methemoglobinemia when concurrently exposed to the following drugs, which could include other local anesthetics:

Examples of Drugs Associated with Methemoglobinemia:

Class:	*Examples:*
Nitrates/Nitrites:	nitric oxide, nitroglycerin, nitroprusside, nitrous oxide
Local anesthetics:	articaine, benzocaine, bupivacaine, lidocaine, mepivacaine, prilocaine, procaine, ropivacaine, tetracaine
Antineoplastic agents:	cyclophosphamide, flutamide, hydroxyurea, ifosfamide, rasburicase
Antibiotics:	dapsone, nitrofurantoin, para-aminosalicylic acid, sulfonamides
Antimalarials:	chloroquine, primaquine
Anticonvulsants:	phenobarbital, phenytoin, sodium valproate
Other drugs:	acetaminophen, metoclopramide, quinine, sulfasalazine carcinogenesis, mutagenesis.

USE IN SPECIFIC POPULATIONS
Pregnancy
Before taking NSAIDs, tell your healthcare provider about all of your medical conditions, including if you are pregnant or plan to become pregnant. Taking NSAIDs at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs after about 30 weeks of pregnancy.

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Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

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If overdose is suspected, discontinue use immediately and seek medical attention. Treatment is supportive and symptomatic. Healthcare professionals may need to monitor fluid and electrolyte balance, correct acid-base disturbances, and manage any complications.

DESCRIPTION
Salicor™ is an external analgesic product containing 10% triethanolamine salicylate as the active ingredient. Triethanolamine salicylate is an organic compound formed between triethanolamine and salicylic acid, where triethanolamine neutralizes the acidity of salicylic acid. This external analgesic is designed for temporary relief of minor pain associated with arthritis, simple backache, muscle strains, sprains, and bruises. Unlike other external analgesics, triethanolamine salicylate has no distinct odor, which improves patient acceptability.

Inactive ingredients: crospovidone, polyisobutylene rubber PSA adhesive

CLINICAL PHARMACOLOGY
Pharmacodynamics
Triethanolamine salicylate is an external analgesic that functions by inhibiting cyclooxygenase (COX) enzymes, which are involved in the production of pro-inflammatory factors such as prostaglandins and thromboxanes. These enzymes play a crucial role in generating pain and inflammation in conditions like arthritis, muscle strains, and sprains. While salicylates, such as aspirin, are known to inhibit COX enzymes, the specific mechanism of triethanolamine salicylate in topical applications may differ slightly. It is generally believed to act similarly to topical NSAIDs, reducing inflammation and pain locally. However, the evidence regarding its selectivity towards COX-2 enzymes is less clear.

Pharmacokinetics
Absorption
Following external administration of Salicor™ to healthy volunteers, no detectable levels of salicylic acid were found in the serum, indicating low systemic absorption. This minimal absorption is advantageous as it reduces the risk of systemic side effects commonly associated with oral salicylates. Studies have shown that urinary recovery of total salicylate during the first 24 hours after external application was only 6.9 mg, which represents approximately 1.4% of the total dose applied.

Distribution
Triethanolamine salicylate is transported and distributed within cells and tissues through various mechanisms. Studies in canines and humans have shown that transdermal absorption of salicylate from triethanolamine salicylate preparations applied to skin is consistent and reproducible, with measurable tissue salicylate levels at the application site. The distribution appears to be concentration-dependent, with tissue salicylate levels directly proportional to the concentrations of the active ingredient in the formulation up to the 10% preparation.

Metabolism
While specific metabolism data for externally applied Salicor™ is limited due to its low systemic absorption, the small amount that does enter the systemic circulation is likely metabolized similarly to other salicylates. The primary metabolic pathways include:
1. Conjugation with glycine to form salicyluric acid (approximately 75%).
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3. Oxidation to gentisic acid and other hydroxylated derivatives (minor pathway).

Free, unmodified salicylate accounts for 10–30% of excreted metabolites, depending on dosage and individual factors like urinary pH. Metabolism primarily occurs in the liver, with some possible local metabolism in skin tissues.

Excretion
Triethanolamine salicylate is primarily excreted through the urine after metabolism. Following external application of a 10% formulation, approximately 1.4% of the total dose is recovered in the urine as salicylate within the first 24 hours, indicating low systemic absorption.

NONCLINICAL TOXICOLOGY
Impairment of Fertility
The potential effect of Salicor™ on fertility has not been studied.

HOW SUPPLIED
Salicor™ is available as the following:
1 carton, 15 systems
NDC 83881-501-15

Avoid contact with the eyes.
Store at 68–77 °F (20–25 °C).
[See USP Controlled Room Temperature]

STORAGE AND HANDLING
Store at room temperature. Keep away from excessive heat and direct sunlight. Salicor™ should be kept out of reach of children.

For more information, contact Clinic Pharma.
info@clinicpharma.com

Manufactured for:

Clinic Pharma

Clinic Pharma
Las Vegas, NV 89121
Printed in the U.S.A.

NDC 83881-501-15

Salicor™

TRANSDERMAL SYSTEM

Triethanolamine Salicylate 10%

- Designed for Active Wear
- Fast-Acting

- Fast-Acting
- All-Night Hold
- Water-Resistant

15 Systems
6 cm x 9.5 cm
(2.4 in x 3.75 in)

DISPENSED BY PRESCRIPTION

Drug Facts

Active ingredient (in each system) ***Purpose***
Triethanolamine Salicylate 10%.....NSAID

Warnings
For external use only

Use
For the temporary relief of pain

Do not use • on the face or rashes, wounds or damaged skin • in the eyes, mouth, or other mucous membranes • on genitals • with a heating pad • right before or after heart surgery • any Salicor™ from a pouch that has not been applied immediately after opening the pouch • over raw surfaces or blistered areas • if the pouch is broken or torn • more than 2 Salicor™ per day unless directed by a doctor • children under 18 years of age

Ask a doctor before use if you have • allergies to external or transdermal products • high blood pressure, heart disease, or kidney disease

When using this product • avoid contact with eyes. If eye contact occurs, rinse thoroughly with water • the risk of heart attack or stroke may increase if you use more than directed or for longer than directed • see insert for more information

Stop use and ask a doctor if condition worsens, symptoms persist for more than 7 days, or symptoms return within a few days after discontinuing use.

If pregnant or breastfeeding, ask a health professional before use. Do not use at 20 weeks of pregnancy or later, as it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** If ingested, seek medical help or contact a Poison Control Center 1-800-222-1222 immediately. Dispose of used Salicor™ by folding the sticky ends together.

Directions

For adults 18 years and older:

- clean and dry the affected area
- locate the tear notch on the edge of the pouch. Tear open at the notch or carefully cut open the pouch with scissors, taking care not to cut the system inside.
- remove the transparent release liner before applying Salicor™ to the skin
- apply one Salicor™ to the affected area of pain and leave it in place for 8 to 12 hours
- apply only one Salicor™ at a time
- if pain persists, the used Salicor™ may be replaced with a new one for up to 8 to 12 more hours
- always remove and properly dispose of the used Salicor™ before applying a new one
- Salicor™ may be cut into smaller sizes with scissors prior to removing the release liner
- safely discard the used Salicor™ (whole or cut pieces) where children and pets cannot access it
- wash hands with soap and water after applying or removing Salicor™

Other information

- some individuals may not experience pain relief until several minutes or hours after applying Salicor™
- avoid storing product in direct sunlight
- store at 68–77 °F (20–25 °C)

Inactive ingaredients

crospovidone, polyisobutylene rubber PSA adhesive

Questions or comments?

Call (800) 224-2048

SALICOR

triethanolamine salicylate patch

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:83881-501
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TEA-SALICYLATE (UNII: H8O4040BHD) (SALICYLIC ACID - UNII:O414PZ4LPZ)	TEA-SALICYLATE	40.2 mg

Inactive Ingredients	
Ingredient Name	**Strength**

2-ETHYLHEXYL ACRYLATE-METHYL ACRYLATE-GLYCIDYL METHACRYLATE-ACRYLIC ACID COPOLYMER (FOR DURO-TAK 387-2353) (UNII: 737PT7E2CY)	
HEPTANE (UNII: 456148SDMJ)	
KOLLIDON SR (UNII: S34RY76LK6)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83881-501-15	15 in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2027	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/22/2025	

Labeler - Clinic Pharma (119158469)

Revised: 10/2025 Clinic Pharma