

ALIVIO- lidocaine patch
Amerise Pharmaceuticals LLC

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.

Alivio 4%

Lidocaine 4% Patch

Transdermal Pain Relief Patch

Active Ingredients

Lidocaine 4% Topical Anesthetic

Use

Temporarily relieves minor pain

Temporarily relieves minor pain

Warnings

For external use only.

Do not use

- more than 1 patch on your body at a time or on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor

When using this product

- use only as directed. Read and follow all directions and warning on this carton
- rare cases of serious burns have been reported with products of this type
- do not apply to wounds or damaged, broken or irritated skin
- do not allow contact with the eyes and mucous membranes
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- do not use at the same time as other topical analgesics
- dispose of used patch in manner that always keep 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
- a transient burning sensation may occur upon applicaiton but generally disappears in several day
- if a severe buring sensation occurs, discontinue use immediately

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 of skin injury, such as pain, 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children over 12 years:

- clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until back separates in middle
- use 1 patch for up to 12 hours

Children 12 years or younger; ask a doctor

Inactive Ingredients

alpha-tocopherol acetate, aluminum hydroxide, aluminum silicate, butylated hydroxytoluene, butyl rubber, isoprene rubber, mineral oil, polyisobutylene, rosin, silicon dioxide, styrene/isoprene/styrene block, titanium dioxide

Distributed in US by:

Amerise Pharmaceuticals LLC

6 Corporate Dr, Cranbury, NJ 08512

Customer Care NO.: 609-721-9587

Email: help@amerisepharma.com

alivio 4%
Transdermal Pain Relief Patch

Transdermal Pain Relief Patch
alivio 4%

APPLYING YOUR PATCH

Drug Facts	Purposes
Active Ingredients Lidocaine 4%	Topical Anesthetic
Use temporarily relieves minor pain	
Warnings For external use only Do not use if more than 1 patch on your body at a time or on cut, irritated or swollen skin or on puncture wounds Do not use more than one week without consulting a doctor	
When using this product Use only as directed. Read and follow all directions and warnings on this carton. Rare cases of serious burns have been reported with products of this type. Do not apply to wounds or damaged, broken or irritated skin. Do not allow contact with the eyes and mucous membranes. Do not bandage lightly or apply local heat (such as heating pads) to the area of use. Do not use at the same time as other topical analgesics. 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. A transient burning sensation may occur upon application but generally disappears in several days. If a severe burning sensation occurs, discontinue use immediately.	
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 of rash (redness, such as pain, swelling, or blistering where the product was applied)	
Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions adults and children over 12 years: clean and dry affected area remove backing from patch by firmly grasping both ends and gently pulling until back separates in middle unroll backing from patch and apply exposed portion of patch to affected area use 1 patch for up to 12 hours children 12 years or younger ask a doctor	
Inactive ingredients alpha-tocopherol acetate, aluminum hydroxide, aluminum silicate, butylated hydroxytoluene, butyl rubber, isoprene rubber, mineral oil, polyisobutylene, rosin, silicon dioxide, styrene/isoprene copolymer/black, titanium dioxide	

AMERISE
Pharmaceuticals LLC

Distributed in US by:
Amerise Pharmaceuticals LLC
6 Corporate Dr. Cranbury, NJ 08512
Customer Care No.: 800-721-9587
E-mail: help@amerisepharm.com

96512 10012 5

RP/C-3242 Rev. 00

Made in India
Neutral Code: HP/Drugs/MNB/06/348

CHILD-RESISTANT PACKAGING
NDC 82589-101-20

Transdermal Pain Relief Patch
alivio 4%

QUANTITY
20
PATCHES

Lidocaine 4% Patch
Desensitizes
Aggravated
Nerves
Each Patch: 3-15/16" x 5 1/2" (10 cm x 14 cm)

No Irritation • No Burning • Penetrates to the Nerves
Fast Acting • Targets Pain • Easy to Apply & Remove

Transdermal Pain Relief Patch
alivio 4%

Logo & Barcode will also be in Blue Colour
Carton with Neutral Label

CHILD-RESISTANT PACKAGING
NDC 82589-101-01

Transdermal Pain Relief Patch
alivio 4%

Lidocaine 4% Patch
Desensitizes
Aggravated
Nerves
Each Patch: 3-15/16" x 5 1/2" (10 cm x 14 cm)

No Irritation • No Burning • Penetrates to the Nerves
Fast Acting • Targets Pain • Easy to Apply & Remove

Transdermal Pain Relief Patch
alivio 4%

APPLYING YOUR PATCH

Drug Facts	Purposes
Active Ingredients Lidocaine 4%	Topical Anesthetic
Use temporarily relieves minor pain	
Warnings For external use only Do not use if more than 1 patch on your body at a time or on cut, irritated or swollen skin or on puncture wounds Do not use more than one week without consulting a doctor	
Directions adults and children over 12 years: clean and dry affected area remove backing from patch by firmly grasping both ends and gently pulling until back separates in middle unroll backing from patch and apply exposed portion of patch to affected area use 1 patch for up to 12 hours children 12 years or younger ask a doctor	
Inactive ingredients alpha-tocopherol acetate, aluminum hydroxide, aluminum silicate, butylated hydroxytoluene, butyl rubber, isoprene rubber, mineral oil, polyisobutylene, rosin, silicon dioxide, styrene/isoprene copolymer/black, titanium dioxide	

AMERISE
Pharmaceuticals LLC

Distributed in US by:
Amerise Pharmaceuticals LLC
6 Corporate Dr. Cranbury, NJ 08512
Customer Care No.: 800-721-9587
E-mail: help@amerisepharm.com

96512 10012 5

RP/C-3242 Rev. 00

Made in India
Neutral Code: HP/Drugs/MNB/06/348

alivio 4%
Transdermal Pain Relief Patch

Transdermal Pain Relief Patch
alivio 4%

APPLYING
YOUR
PATCH



1. Peel patch from inside



2. Peel off the remaining backing layer and press the patch in place

Drug Facts	Purposes
Active ingredients Lidocaine 4%	Topical Anesthetic
Use temporarily relieves minor pain	
Warnings For external use only Do not use on more than 1 patch on your body at a time or on cut, irritated or swollen skin or on puncture wounds Do not use for more than one week without consulting a doctor	
When using this product use only as directed. Read and follow all directions and warnings on this carton. Rare cases of serious burns have been reported with products of this type. Do not apply to wounds or damaged, swollen or irritated skin. Do not allow contact with the eyes and mucous membranes. Do not bandage tightly or apply local heat (such as heating pads) to the area of use. Do not use at the same time as other topical analgesics. Dispose of used patch in manner that always keeps protected 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. A transient burning sensation may occur upon application but generally disappears in several days. If a severe burning sensation occurs, discontinue use immediately.	
Stop use and ask a doctor if: irritation worsens, redness is present, irritation develops, or 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.	
Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions Adults and children over 12 years: Clean and dry affected area. Remove backing from patch by firmly grasping both ends and gently pulling until back separates in middle. Carefully remove smaller portions of backing from the patch and apply exposed portion of patch to affected area. Use 1 patch for up to 12 hours. Children 12 years or younger: ask a doctor.	
Inactive ingredients alpha-tocopherol acetate, aluminum hydroxide, stannous fluoride, butylated hydroxytoluene, butyl rubber, isoprene rubber, mineral oil, polybutylene, wax, zinc oxide, styrene/acrylonitrile copolymer, titanium dioxide.	



AMERISE
Pharmaceuticals LLC

Distributed in US by:
Amerise Pharmaceuticals LLC
4 Corporate Dr., Cranbury, NJ 08512
Customer Care No.: 609-731-9287
E-mail: help@amerisepharm.com

Made in India
Neutral Code: HP/Drugs/MNB/06/348



1 98052 10032 3

© C-3242 Rev. 00

MAX STRENGTH LIDOCAINE
CHILD-RESISTANT PACKAGING
NDC 82598-101-03

Transdermal Pain Relief Patch
alivio 4%

QUANTITY

3

N PATCHES

Lidocaine 4% Patch
Desensitizes Aggravated Nerves
Each Patch: 3-15/16" x 5 1/2" (10 cm x 14 cm)

No Irritation • No Burning • Penetrates to the Nerves
Fast Acting • Targets Pain • Easy to Apply & Remove

Transdermal Pain Relief Patch
alivio 4%

Logo & Barcode will also be in Blue Colour

Carton with Neutral Label

ALIVIO

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82598-101
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	

ALUMINUM SILICATE (UNII: T1FAD4SS2M)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MINERAL OIL (UNII: T5L8T28FGP)	
ROSIN (UNII: 88S87KL877)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER (UNII: K7S96QM8DV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ISOPRENE (UNII: 0A62964IBU)	
ISOBUTYLENE (UNII: QA2LMR467H)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82598-101-20	20 in 1 CARTON	06/17/2022	
1	NDC:82598-101-01	1 in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:82598-101-03	3 in 1 CARTON; Type 0: Not a Combination Product	06/16/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/16/2022	

Labeler - Amerise Pharmaceuticals LLC (089951382)

Revised: 11/2022

Amerise Pharmaceuticals LLC