

**PRO COMFORT 8 HOURS PATCH- lidocaine patch 4% patch
CARE LIVING DIAGNOSTICS 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.

Product Information



Active Ingredient

Lidocaine 4%

Purpose

Topical Anesthetic

Uses

for the temporary relief of pain

Warnings

For external use only

Do not use

- more than 1 patch on your body at a time
- on puncture wounds,
- on cuts, irritated or swollen skin
- 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.
- do not allow contact with the eyes
- 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 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
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness or irritation develops
- 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 (1-800-222-1222).

Directions

Adults and children over 12 years:

- wash and dry affected area
- Peel off the backing film from one side of the patch carefully
- Apply the exposed portion of the patch to the affected area
- Gently press the patch with your hand to fit the affected area completely
- Do not exercise vigorously during use to prevent the patch from falling off
- use only 1 patch for a maximum of 8 hours

children under 12 years of age: Ask a doctor before use

Other Information

store at room temperature 15°-30°C (59°-86°F).

Inactive ingredients

aluminum glycinate, glycerin, methyl acrylate, polyacrylic acid, polysorbate 80, propylene

glycol, sodium polyacrylate, tartaric acid, poval, alcohol, water

Questions or Comments?

E-mail: info@carelivingusa.com

Child-Resistant Packaging Manufactured for

CARE LIVING DIAGNOSTICS INC.

[Www.carelivingusa.com](http://www.carelivingusa.com)

Made in China

Active Ingredient

Lidocaine 4%

Purpose

Topical anesthetic

Uses

for the temporary relief of pain

Warnings

For external use only

Do not use

- more than 1 patch on your body at a time
- on puncture wounds,
- on cuts, irritated or swollen skin
- 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.
- do not allow contact with the eyes
- 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 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
- symptoms persist for more than 7 days or clear up and occur again within a few days
- redness or irritation develops
- 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 (1-800-222-1222)

Directions**Adults and children 12 years of age and older:**

- Wash and dry the affected area.
- Peel off the backing film from one side of the patch carefully.
- Apply the exposed portion of the patch to the affected area.
- Gently press the patch with your hand to fit the affected area completely.
- Do not exercise vigorously during use to prevent the patch from falling off.
- Use only 1 patch for a maximum of 8 hours.

children under 12 years of age: Ask a doctor before use.

Other Information

store at room temperature 15°-30°C (59°-86°F).

Inactive ingredients

aluminum glycinate, glycerin, methyl acrylate, polyacrylic acid, polysorbate 80, propylene glycol, sodium polyacrylate, tartaric acid, poval, alcohol, water

Questions or Comments?

E-mail: info@carelivingusa.com

Manufactured for:

CARE LIVING DIAGNOSTICS INC

www.carelivingusa.com

Made in China

Dosage

0.246 g in 1 PATCH, 5 PATCH in 1 CARTON



Pro Comfort 8 Hour Lidocaine Patch

PRO COMFORT 8 HOURS PATCH			
lidocaine patch 4% patch			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83568-4643
Route of Administration	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	
DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)				
TARTARIC ACID (UNII: W4888I119H)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
UREA (UNII: 8W8T17847W)				
ALCOHOL (UNII: 3K9958V90M)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83568-4643-5	5 in 1 BOX	08/01/2023	
1	NDC:83568-4643-1	4 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	08/01/2023		

Labeler - CARE LIVING DIAGNOSTICS INC (125354643)

Revised: 7/2023

CARE LIVING DIAGNOSTICS INC