

FLANAX BACK PAIN RELIEF- lidocaine patch
Belmora 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.

FLANAX BACK PAIN RELIEF PATCH

Drug Facts

Active ingredients

Lidocaine 4%

Purpose

Topical Anesthetic

Uses

Temporarily relieves minor pain

Warnings

For external use only.

Do not use if pouch is damaged or opened.

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 warnings on this pouch
- 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 keeps product away from children and pets. Used patches still contain the drug products 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 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.

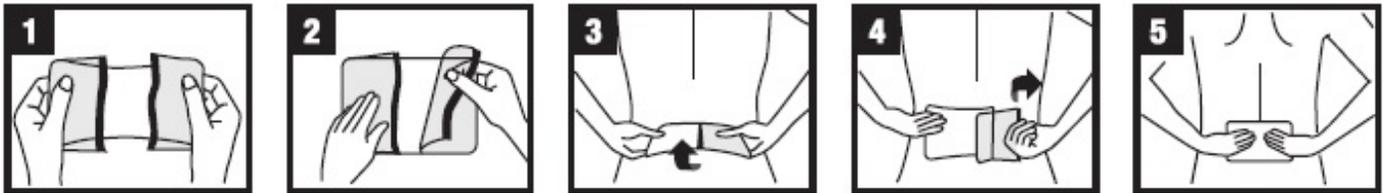
Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children over 12 years: • Clean and dry affected area • Carefully remove backing film from patch • Apply one patch to affected area • Do not use more than 2 patches in 24 hours unless, directed by a doctor.

Children under 12 years: ask a doctor.

How to apply



- Remove backing from patch by firmly grasping both ends and gently pull backing to separate it in the middle.
- Carefully remove one portion of backing from patch and apply exposed portion of patch to affected area.
- Once exposed portion of patch is positioned, remove remaining backing to completely apply patch to affected area.

Inactive Ingredients

Glycerin, Sodium Polyacrylate, Dihydroxyaluminum Aminoacetate, Disodium Ethylenediaminetetraacetic Acid, Kaolin, Titanium Dioxide, Polysorbate 80, Propylene Glycol, Tartaric Acid, Polyacrylic Acid, Polyvinylpyrrolidone K90, Methylparaben, Propylparaben, Water

LONGER LASTING PAIN RELIEF

• **For back, neck, leg & arm pain relieving ointment on a breathable adhesive pad**

Questions/Comments?

www.flanax.com

Call 1 888 779 2877 9AM-5PM EST

Distributed by: Belmora LLC

2011 Crystal Dr. Suite 400, Arlington, VA 22202

Packaging

 Cut along dotted line



FLANAX

PARCHE DE ALIVIO DEL DOLOR DE ESPALDA/
BACK PAIN RELIEF PATCH

**EL ALIVIO QUE
DURA MÁS/
LONGER LASTING
PAIN RELIEF**



PARCHE DE LIDOCAÍNA/
LIDOCAINE PATCH

- ✓ **Ungüento en una almohadilla adhesiva transpirable para aliviar el dolor de espalda, cuello, piernas y brazos**
- ✓ **For back, neck, leg & arm pain relieving ointment on a breathable adhesive pad**

1 Parche/Patch | 3-15/16" x 5-1/2" (10 cm x 14 cm)

4% de Lidocaína/4% Lidocaine

Drug Facts

Active ingredients	Purpose
Lidocaine 4%	Topical Anesthetic

Uses Temporarily relieves minor pain

Warnings For external use only.

Do not use if pouch is damaged or opened.

Do not use • More than 1 patch on your body at a time or on cut, irritated or swollen skin

Información sobre el medicamento

Ingrediente activo	Propósito
Lidocaína 4%	Anestésico tópico

Usos Alivia temporalmente dolores menores

Advertencias Para uso externo solamente

No usar si el envase está dañado o abierto.

No usar • Más de un parche en su cuerpo a la vez o sobre piel cortada, irritada o hinchada

- 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 warnings on this pouch
- 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 keeps product away from children and pets. Used patches still contain the drug products 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 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.

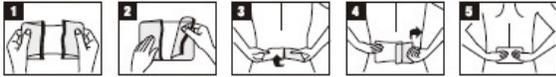
Keep out of reach of children and pets. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children over 12 years: • Clean and dry affected area • Carefully remove backing film from patch • Apply one patch to affected area • Do not use more than 2 patches in 24 hours unless, directed by a doctor.

Children under 12 years: ask a doctor.

How to apply



- Remove backing from patch by firmly grasping both ends and gently pull backing to separate it in the middle.
- Carefully remove one portion of backing from patch and apply exposed portion of patch to affected area.
- Once exposed portion of patch is positioned, remove remaining backing to completely apply patch to affected area.

Inactive Ingredients

Glycerin, Sodium Polyacrylate, Dihydroxyaluminum Aminoacetate, Disodium Ethylenediaminetetraacetic Acid, Kaolin, Titanium Dioxide, Polysorbate 80, Propylene Glycol, Tartaric Acid, Polyacrylic Acid, Polyvinylpyrrolidone K90, Methylparaben, Propylparaben, Water



- En heridas causadas por pinchazos • Durante más de una semana sin consultar a un médico

Cuando use este producto

- Úselo solamente según se le haya indicado. Lea y siga todas las instrucciones y advertencias en este envase
- Casos raros de serias quemaduras se han reportado con productos de este tipo
- No lo aplique a heridas o piel dañada, lacerada o irritada
- No permita el contacto con los ojos o membranas mucosas
- No aplicar vendas con firmeza o calor local (tales como almohadillas calóricas) al área en la que se use el producto
- No lo use al mismo tiempo que con otros analgésicos tópicos
- Deseche los parches usados de manera que siempre se mantenga el producto lejos de los niños y mascotas. Los parches usados contienen todavía los productos farmacológicos que pueden producir efectos adversos serios si un niño o mascota mastica o se traga ese parche

Deje de usar el producto y consulte a un médico si

- La condición se empeora • Hay enrojecimiento • Hay hinchazón
- Los síntomas persisten durante más de 7 días o desaparecen y aparecen de nuevo dentro de pocos días
- Ud. tiene señales de heridas de la piel, tales como dolor, hinchazón o ampollas en el lugar donde fue aplicado el producto

Si está embarazada o en período de lactancia, pregunte a un profesional de la salud antes de usar el producto. Manténgalo fuera del alcance de los niños. Si se traga el producto, obtenga ayuda médica o póngase en contacto con un Centro de Control de Envenenamientos inmediatamente.

Instrucciones

Adultos y niños mayores de 12 años: • Limpie y seque el área dañada • Retire cuidadosamente la lámina de protección del parche • Aplique un parche en el área afectada • No use más de 2 parches en 24 horas a menos que el médico se lo haya indicado

Niños menores de 12 años: consulte con un médico

Cómo aplicarlo



- Retire el respaldo del parche sujetando firmemente ambos extremos y retirando delicadamente el respaldo para separarlo en la parte del medio
- Retire cuidadosamente una porción del respaldo del parche y aplique la porción no cubierta del parche al área afectada
- Una vez que la porción no cubierta del parche se haya aplicado, retire la parte restante del respaldo para aplicar todo el parche al área afectada

Ingredientes Inactivos

glicerina, poliacrilato de sodio, aminoacetato de dihidroxialuminio, ácido etilendiaminotetraacético disódico, caolín, dióxido de titanio, polisorbato 80, propilenglicol, ácido tartárico, polivinilpirrolidona K90, metilparabeno, propilparabeno, agua

Questions/Comments?

¿Preguntas/Comentarios?

www.flanax.com

Llamar al 1 888 779 2877, de lunes a viernes de 9 am a 5 pm, hora del Este

Call 1 888 779 2877 9AM-5PM EST

Distributed by/Distribuido por: Belmora LLC,
3303 Wilson Blvd, Suite 700, Arlington VA 22201

FLANAX BACK PAIN RELIEF

lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-333
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g
---	-----------	-----

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
KAOLIN (UNII: 24H4NWX5CO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TARTARIC ACID (UNII: W4888I119H)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-333-01	1 in 1 POUCH; Type 0: Not a Combination Product	12/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/15/2021	

Labeler - Belmora LLC (112753244)

Revised: 12/2021

Belmora LLC