

SOLMARA- menthol, unspecified form and lidocaine patch
Spring Hill Therapeutics 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.

Solmara

Drug Facts

Active Ingredients	Purpose
Menthol 5.00%	Topical Analgesic
Lidocaine 4.00%	Topical Anesthetic

Uses

For the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness.

Warnings

Only for external use. Use only as directed or by a health professional.

Do not use: on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucous membranes.

Do not cover with bandage.

Keep out of the reach of children. Consult physician for children under 12.

Consult your physician: if pregnant or pain persists or worsens.

Directions

Adults and children 12 years and over. Apply patch to affected area 1 to 2 times daily or as directed.

Instruction for Use

Clean and dry the affected area

Open pouch and remove one patch

Remove any protective film and apply directly to affected area of pain

Wash hands with soap and water after applying patch

Reseal pouch containing unused patches after each use

Other Ingredients

Methacrylic acid, ethylhexylacrylate, bentonite, sodium stearate.

FOR QUESTIONS CALL 813-388-8735

PRINCIPAL DISPLAY PANEL - 15 Patch Carton

NDC 69833-011-15

Solmara

Lidocaine 4%,Menthol 5%

15

Patches

NDC 69833-011-15



Solmara

Lidocaine 4%, Menthol 5%

15
Patches

Solmara



Drug Facts

Active Ingredients	Purpose
Menthol 5.00%	Topical Analgesic
Lidocaine 4.00%	Topical Anesthetic

Uses:

For the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness.

Warnings:

Only for external use. Use only as directed or by a health professional.

Do not use: on open wounds, cuts, damaged or infected skin as well as in the eyes, mouth, genitals, or any other mucous membranes.

Do not cover with bandage.

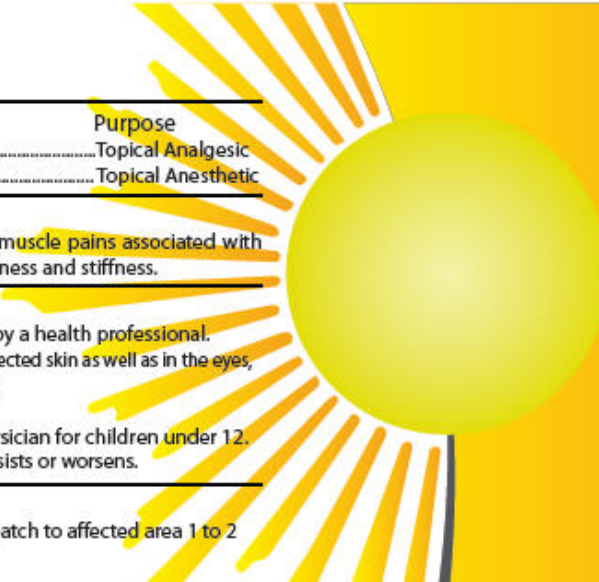
Keep out of the reach of children. Consult physician for children under 12.

Consult your physician: if pregnant or pain persists or worsens.

Directions:

Adults and children 12 years and over. Apply patch to affected area 1 to 2 times daily or as directed.

Instruction for Use:



mara

Instructions for Use:

- Clean and dry the affected area
- Open pouch and remove one patch
- Remove any protective film and apply directly to affected area of pain
- Wash hands with soap and water after applying patch
- Reseal pouch containing unused patches after each use

Other Ingredients:

Methacrylic acid, ethylhexylacrylate, bentonite, sodium stearate.



8270 Woodland Center Blvd.
Tampa, FL 33614
FOR QUESTIONS CALL 813-388-8735



SOLI



SOLMARA

menthol, unspecified form and lidocaine patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69833-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol, Unspecified Form (UNII: L7T10EIP3A) (Menthol, Unspecified Form - UNII:L7T10EIP3A)	Menthol, Unspecified Form	5 g
Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	4 g

Inactive Ingredients

Ingredient Name	Strength
2-Ethylhexyl Acrylate (UNII: HR49R9S6XG)	
Methacrylic Acid (UNII: 1CS02G8656)	
Bentonite (UNII: A3N5ZCN45C)	
Sodium Stearate (UNII: QU7E2XA9TG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69833-011-15	5 in 1 CARTON		
1		3 in 1 POUCH; 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

07/20/2015

Labeler - Spring Hill Therapeutics LLC (079813250)

Revised: 7/2015

Spring Hill Therapeutics LLC