AVALIN EXTERNAL ANALGESIC PATCH- lidocaine, menthol patch RxChange Co.

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.

Avalin External Analgesic Patch

Active ingredients

Lidocaine 4%

Menthol 1%

Purpose

External Analgesic

Uses

For the temporary relief pain associated with • minor cuts • scrapes • minor skin imitations

Warnings

For external use only

Do not use

- in large quantities, particularly over raw surfaces or blistered areas
- other than directed by a doctor on open wounds or damaged skin
- with a bandage to cover the surface for longer than 5 consecutive days

Ask a doctor before use

if used for children under 12.

When using this product

avoid contact with the eyes.

Stop use and ask a doctor

- condition worsens symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

If swallowed, get a medical help or contact Poison Control Center right away.

Directions

- Adults and children 2 years of age and older: Apply to the affected area not more than 3 to 4 times daily.
- Children under 2 years of age: Consult a doctor.

- Clean and dry affected area.
- Remove patch from backing and apply to affected area.
- Use one patch at a time.
- Leave patch on affected area for up to 8-hours at a time

Other information

Store in dry area between 59-79 F(15-26 C)

Inactive ingredients

acrylic acid, aluminum hydroxide, carmellose sodium, 2-ethylhexyl acrylate, glycerin, isopropyl myristate, methyl acrylate, nonoxynol-30, polyacrylate, polyacrylic acid, polysorbate 80, sorbitan sesquioleate, starch, talc, tartaric acid, titanium dioxide, water

Questions or comments?

Please call (818) 545-1177

Product Label

AvaLin PAIN RELIEVING PATCH

NDC 33358-901-15



For the temporary relief of pain associated with minor cuts, scrapes, and minor skin irritations.

15 Patches

Drug Facts	
Active ingredients	Purpose
Lidocaine 4% Menthol 1% }	External Analgesic
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Questions or comments? Please call (818) 545-1177	

AvaLin PAIN RELIEVING PATCH

Manufactured for: RxChange Co. Burbank, CA 91504 Made in China Patent pending



AVALIN EXTERNAL ANALGESIC PATCH

lidocaine, menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33358-901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE	40 mg in 1 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
ACRYLIC ACID (UNII: J94PBK7X8S)			
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)			
CROSCARMELLOSE SODIUM (UNII: M28 O L 1HH48)			
2-ETHYLHEXYL ACRYLATE (UNII: HR49 R9 S6 XG)			
GLYCERIN (UNII: PDC6A3C0OX)			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)			

METHYL ACRYLATE (UNII: WC487PR91H)	
NONOXYNOL-30 (UNII: JJX07DG188)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W48881119H)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
WATER (UNII: 059QF0KO0R)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:33358-901-15	15 in 1 CARTON			
1		100 g in 1 PATCH			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	0 1/29/20 15	

Labeler - RxChange Co. (781126805)

Revised: 1/2015 RxChange Co.