

SITEROL- lidocaine hcl, menthol patch
Binger Consulting Corporation

Siterol

Drug Facts

Active ingredient

Lidocaine HCL 3.99%

Menthol 1.00%

Purpose

Topical Analgesic

External Analgesic

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

Uses

- temporary relief of pain associated with minor cuts, scrapes, and minor skin irritations

Warnings

For external use only

Do not use

- if pregnant or breastfeeding, consult physician prior to use
- in large quantities, particularly over raw surfaces or blistered areas

When using this product

- use only as directed • do not bandage tightly • avoid contact with eyes
- do not apply to open wounds or damaged skin

Stop use and ask a doctor if

- symptoms persist for more than seven days, discontinue use and consult physician
- swallowed, consult physician

Directions

How to apply • clean and dry affected area • remove patch from backing and apply to affected area • use only one patch at a time, and maximum of four patches/day • leave

patch on affected area for upto 8-hours • do not use patches for longer than five consecutive days

Other ingredients aloe barbadensis leaf (aloe vera juice) gel, aqua (deionized water), arnica montana extract, boswellia serrata extract, camellia sinensis leaf (green tea) extract, carbomer, ethylhexylglycerin, glycerin, isopropyl myristate, PEG-8, phenoxyethanol, polysorbate-80, sodium lauryl sulfate, triethanolamine, FD C blue 1, FD C yellow 5

Questions or comments? call weekdays from 9 AM to 5 PM PST 888-501-5651

Other information store below 25°C (77° F), avoid direct sunlight

Packaging



SITEROL			
lidocaine hcl, menthol patch			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69440-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	3.99 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	1 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARNICA MONTANA WHOLE (UNII: O80TY208ZW)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BOSWELLIA SACRA WHOLE (UNII: 8O600AZL0W)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEG-8 GLYCERYL ISOSTEARATE (UNII: 74QQ5X3KL1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69440-007-15	15 in 1 BOX	01/01/2015	
1		100 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 Drug	M017	01/01/2015	

Labeler - Binger Consulting Corporation (079635976)

Establishment			
Name	Address	ID/FEI	Business Operations
Active Intelligence, LLC		080416593	manufacture(69440-007)

