SITEROL- lidocaine hcl, menthol patch
Binger Consulting Corporation

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.

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 not final	part348	01/01/2015	

Labeler - Binger Consulting Corporation (079635976)

Establishment

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