LIP BALM SUNSCREEN SPF 4 CHERRY FLAVOR- spf4 cherry lip balm stick Walgreen 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.

Drug Facts

Active ingredients

Padimate O, 1.5%

Purpose

Sunscreen

\Box Uses

• Helps prevent sunburn

□ Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **□not** skin cancer or early skin aging.

IFor external use only

□Do not use □ on damaged or broken skin

When using this product, keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

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

Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating
- children under 6 months of age: Ask a doctor

Other information

• protect this product from excessive heat and direct sunlight

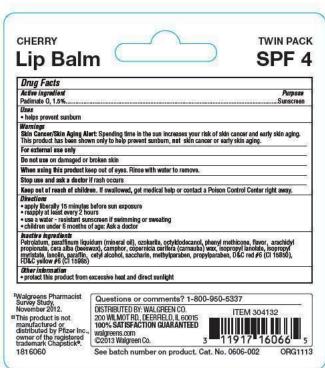
Inactive ingredients

Petrolatum, paraffinum liquidum (mineral oil), ozokerite, octyldodecanol, phenyl methicone, flavor,

arachidyl propionate, cera alba (beeswax), camphor, copernicia cerifera (carnauba) wax, isopropyl lanolate, isopropyl myristate, lanolin, paraffin, cetyl alcohol, saccharin, methylparaben, propylparaben, D&C red #6 (CI 15850), FD&C yellow #6 (CI 15985)







LIP BALM SUNSCREEN SPF 4 CHERRY FLAVOR

spf4 cherry lip balm stick

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-6060

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)
PADIMATE O (1.5 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
PETROLATUM (UNII: 4T6H12BN9U)		
ARACHIDYL PROPIONATE (UNII: QV5DAH3MSB)		
WHITE WAX (UNII: 7G1J5DA97F)		
CAMPHOR (NATURAL) (UNII: N20 HL7Q941)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
D&C RED NO. 6 (UNII: 481744AI4O)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
METHYLPARABEN (UNII: A218 C7H19 T)		
OCTYLDODECANOL (UNII: 461N1O614Y)		

PARAFFIN (UNII: 19 O 0 E 3 H 2 Z E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SACCHARIN (UNII: FST467XS7D)	
LANOLIN (UNII: 7EV65EAW6H)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NO J4R)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0363-6060-02	2 in 1 BLISTER PACK			
1	NDC:0363-6060-01	4 g in 1 CONTAINER			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part352	09/01/2013			

Labeler - Walgreen Co (008965063)

Registrant - Lee Pharmaceuticals (056425432)

Establishment				
Name	Address	ID/FEI	Business Operations	
Lee Pharmaceuticals		056425432	manufacture(0363-6060)	

Revised: 11/2013 Walgreen Co