

SUNSCREEN LIP BALM- padimate o,octinoxate stick
NingBo Huize Commodity Co.,Ltd.

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.

sunscreen lip balm

Active Ingredient

Octylmethoxycinnamate 4%,
2-ethylhexyl 4-(dimethylamino)benzoate 7.5%

Purpose

Sunscreen

Use

Helps prevent sunburn.

If used as directed with other sun protection

measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

WARNINGS

For external use only.

When using this products

■ apply to the lips

■ Lips are the softest part of your face and the most exposed to Constant exposure to sun ,air,dust,pollution,bacteria and a variety of food items,makes the lips dry

■ They need a little extra care and protection to retain their softness

■ These lip balm ingredients are harmless to your tender skin which makes lip balm an absolutely safe product to use.

Stop use and ask a doctor if rash occurs

keep out of reach of children

Keep out of reach of children. If product is swallowed, get

medical help or contact a Poison Control Center right away.

Directions

Directions

■ Apply liberally 15 minutes before sun exposure

■ after 80 minutes of swimming or sweating, immediately after towel drying.

■ To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher

■ at least every 2 hours.

■ Spending time in the sun increases your risk of skin cancer and early skin aging

Inactive ingredients

Synthetic wax,Hydrogenated polyisobutene,liquid paraffin ,flavor,Vitamin E

label

Drug Facts		Drug Facts(continued)	
<p>Active Ingredient</p> <p>Octylmethoxycinnamate 4%, 2-ethylhexyl 4-(dimethylamino)benzoate 7.5%</p>		<p>Purpose</p> <p>Sunscreen</p>	
<p>Uses</p> <ul style="list-style-type: none"> ■ Helps prevent sunburn. ■ If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun. 		<p>Directions</p> <ul style="list-style-type: none"> ■ Apply liberally 15 minutes before sun exposure ■ after 80 minutes of swimming or sweating, immediately after towel drying. ■ To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher ■ at least every 2 hours. ■ Spending time in the sun increases your risk of skin cancer and early skin aging 	
<p>Warnings</p> <p>For external use only.</p>		<p>other information: store at 20-25 °C (68-77 °F)</p>	
<p>Do not use</p> <ul style="list-style-type: none"> ■ on damaged or broken skin ■ in or near the eyes 			
<p>When using this products</p> <ul style="list-style-type: none"> ■ apply to the lips ■ Lips are the softest part of your face and the most exposed to Constant exposure to sun ,air,dust,pollution,bacteria and a variety of food items,makes the lips dry ■ They need a little extra care and protection to retain their softness ■ These lip balm ingredients are harmless to your tender skin which makes lip balm an absolutely safe product to use. 		<p>Inactive ingredients</p> <p>Synthetic wax,Hydrogenated polyisobutene,liquid paraffin ,flavor,Vitamin E</p>	
<p>Stop use and ask a doctor if rash occurs</p>			
<p>Keep out of reach of children .If swallowed ,get medical help or contact a Poison on Control Center immediately</p>			

SUNSCREEN LIP BALM

padimate o,octinoxate stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71011-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 g in 100 g
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	7.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
PARAFFIN (UNII: I9O0E3H2ZE)	

VITAMIN A MYRISTATE (UNII: 7H32T49054)	
1.ALPHA.,24S-DIHYDROXYVITAMIN D2 (UNII: 2900I92Z36)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71011-002-01	10 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
2	NDC:71011-002-02	13 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
3	NDC:71011-002-03	14 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
4	NDC:71011-002-04	15 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
5	NDC:71011-002-05	16 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
6	NDC:71011-002-06	19 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
7	NDC:71011-002-07	20 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
8	NDC:71011-002-08	25 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
9	NDC:71011-002-09	30 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
10	NDC:71011-002-11	3 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
11	NDC:71011-002-12	4 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
12	NDC:71011-002-13	5 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
13	NDC:71011-002-14	6 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
14	NDC:71011-002-15	7 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
15	NDC:71011-002-16	8 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	
16	NDC:71011-002-17	9 g in 1 PACKAGE; Type 0: Not a Combination Product	10/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/08/2016	

Labeler - NingBo Huize Commodity Co.,Ltd. (544434795)

Establishment

Name	Address	ID/FEI	Business Operations
NingBo Huize Commodity Co.,Ltd.		544434795	manufacture(71011-002)