

YES TO CARROTS SWEET FIG LIP BUTTER WITH SPF 15- zinc oxide stick
Autumn Harp, Inc

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.

Yes To Carrots Sweet Fig Lip Butter with SPF 15

Active Ingredient

Zinc Oxide (7.6%)

□ Purpose

Sunscreen

□ Uses

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. 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 Doctor** if rash occurs. **Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

□ Directions

Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if swimming or sweating. Reapply at least every two hours. Children under 6 months: Ask a doctor.

Sun Protection Measures

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10am - 2pm. Wear long sleeved shirts, pants, hats and sun-glasses.

□ Inactive Ingredients

Inactive Ingredients: Beeswax, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Helianthus Annus (Sunflower) Seed Oil, Flavor, Copernicia Cerifera (Carnauba) Wax, Jojoba Esters, Butyrospermum Parkii (Shea) Butter*, Ammonium Glycyrrhizate, Tocopherol, Ficus Carica (Fig) Extract, Limonene. * Certified Organic Ingredient

□ Other Information

Protect this product from excessive heat and direct sun.

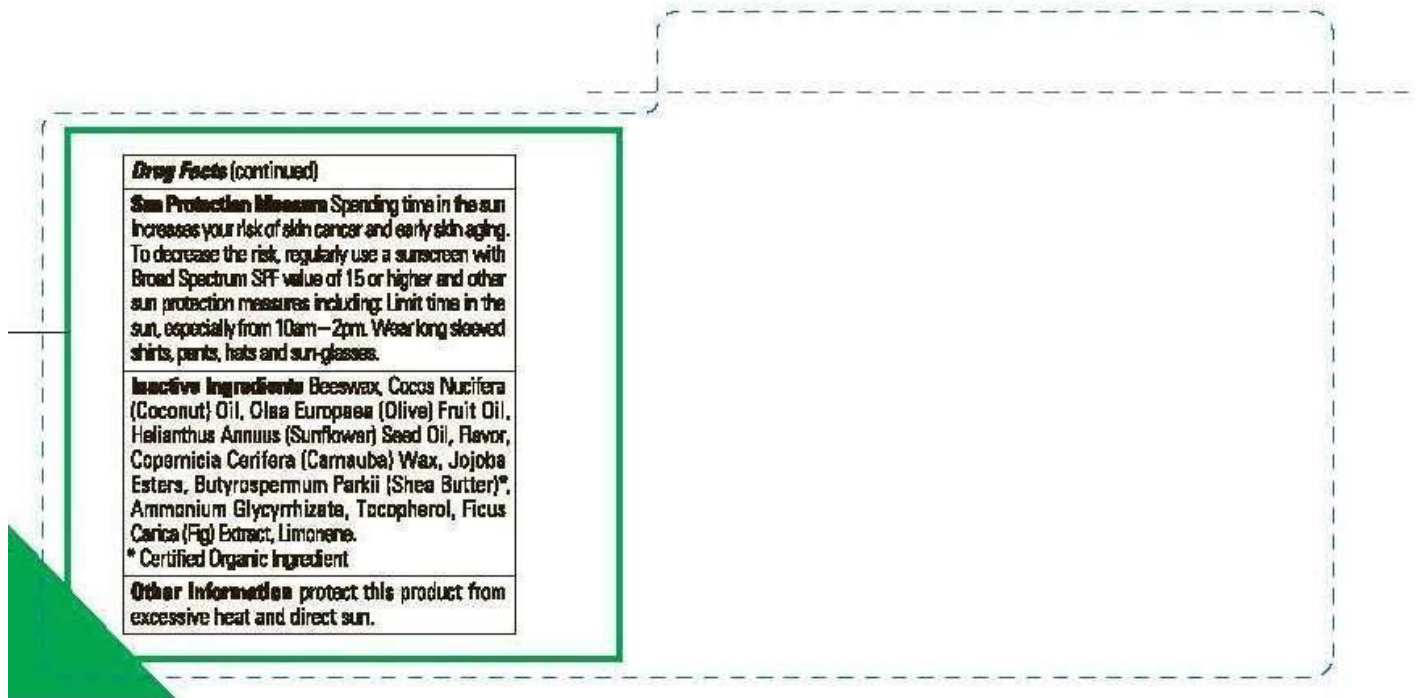
Principal Display Panel

Image Components



NC
sta
in t

Bottom Ply



Drug Facts (continued)

Sun Protection Measures Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10am–2pm. Wear long sleeved shirts, pants, hats and sun-glasses.

Inactive Ingredients Beeswax, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Helianthus Annuus (Sunflower) Seed Oil, Flavor, Copernicia Cerifera (Carnauba) Wax, Jojoba Esters, Butyrospermum Parkii (Shea Butter)*, Ammonium Glycyrrhizate, Tocopherol, Ficus Carica (Fig) Extract, Limonene.
* Certified Organic Ingredient

Other Information protect this product from excessive heat and direct sun.

YES TO CARROTS SWEET FIG LIP BUTTER WITH SPF 15

zinc oxide stick

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:51514-0320

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
COCONUT OIL (UNII: Q9L0O73W7L)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
JOJOBA OIL (UNII: 724GKU717M)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
FIG (UNII: TGD87RI2U)	
SHEA BUTTER (UNII: K49155WL9Y)	
TOCOPHEROL (UNII: R0ZB2556P8)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
FICUS CARICA LEAF (UNII: 59K6U5G4K7)	
SOYBEAN OIL (UNII: 241ATL177A)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LIMONENE, (+/-)- (UNII: 9MC3I34447)	
CITRAL (UNII: T7EU0O9VPP)	
EUGENOL (UNII: 3T8H1794QW)	
GERANIOL (UNII: L837108USY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	FIG	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0320-1	4.25 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/01/2013	

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc		064187883	manufacture(51514-0320)

Revised: 10/2013

Autumn Harp, Inc