

MEDICATED LIP BALM- dimethicone, oxybenzone, and 2-ethylhexyl dimethyl paba cream
Xtreme Tools International, 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.

MEDICATED LIP BALM

Active ingredients

Dimethicone 2.0%

Oxybenzone 2.5%

2-Ethylhexyl Dimethyl PABA 6.6%

Purpose

Dimethicone 2.0% - Lip protectant

Oxybenzone 2.5%- Sunscreen

2-Ethylhexyl Dimethyl PABA 6.6%- Sunscreen

Uses

- Temporarily protects and relieve chapped or cracked lips
- 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.

For external use only

Do not use on broken or damaged 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. If 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 years of age: Ask a doctor

Inactive ingredients

Prunus Arnygdalus Dulcis (Sweet Almond) Oil, Anthemis Nobilis Flower Extract, Hydrogenated Vegetable Oil, Beeswax, Shea Butter Ethyl Esters, Cocos Nucifera (Coconut) Oil, Argania Spinosa

(Argan) Nut Oil, Tocopheryl Acetate, Organic flavors.

Other information

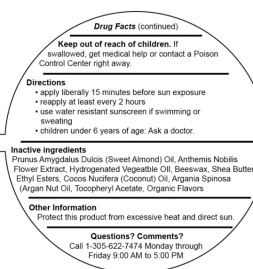
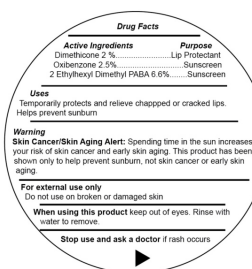
- protect this product from excessive heat and direct sun.

Questions or comments?

Call 1-305-622-7474 Monday through Friday 9:00 AM to 5:00 PM

PACKAGE LABEL

5 gram in Jar ; NDC 74553-004-01



MEDICATED LIP BALM

dimethicone, oxybenzone, and 2-ethylhexyl dimethyl paba cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74553-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	2 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	2.5 g in 100 g
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	6.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALMOND OIL (UNII: 66YXD4DKO9)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0O73W7L)	

ARGAN OIL (UNII: 4V59G5UW9X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SHEA BUTTER ETHYL ESTERS (UNII: V2CI786FPG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74553-004-01	5 g in 1 JAR; Type 0: Not a Combination Product	10/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	10/14/2020	

Labeler - Xtreme Tools International, Inc (125398904)

Registrant - Xtreme Tools International, Inc (125398904)

Establishment

Name	Address	ID/FEI	Business Operations
Xtreme Tools International, Inc		125398904	manufacture(74553-004)

Revised: 10/2020

Xtreme Tools International, Inc