

LIP REMEDY MEDICINAL LIP BALM BLUE- petrolatum stick
LIP REMEDY MEDICINAL LIP BALM GREEN- petrolatum stick
LIP REMEDY MEDICINAL LIP BALM RED- petrolatum stick
GANZ U.S.A., LLC

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.

time & again[®]
LIP REMEDY medicinal lip balm
with Menthol and Cocoa Seed Butter

Drug Facts

Active ingredients

Petrolatum 32.3%

Purposes

Skin Protectant

Uses

- temporarily protects and helps relieve chapped, cracked lips
- temporarily protects lips from drying effects of wind and cold weather

Warnings

- For external use only

When using this product keep out of eyes.

Stop use and ask a doctor if

- irritation or rash occurs
- symptoms persist for more than 7 days or clear up and occur again within a few days

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

Directions

- Apply as needed.

Other information

- store at 20-25°C (68-77°F)
- this is a personal care item and should be used by one individual
- You may report a serious adverse reaction to this product to: GANZ U.S.A., LLC, #043, 60 Industrial Parkway, Cheektowaga, New York, 14227-9903

Inactive ingredients

isopropyl lanolate, lanolin, ozokerite wax, euphorbia cerifera (candelilla) wax, isopropyl myristate, polybutene, diisopropyl adipate, myristyl myristate, flavor, theobroma cacao (cocoa) seed butter, camphor, menthol, phenol, yellow 10 lake, red 6 lake, saccharin, menthoxypropanediol

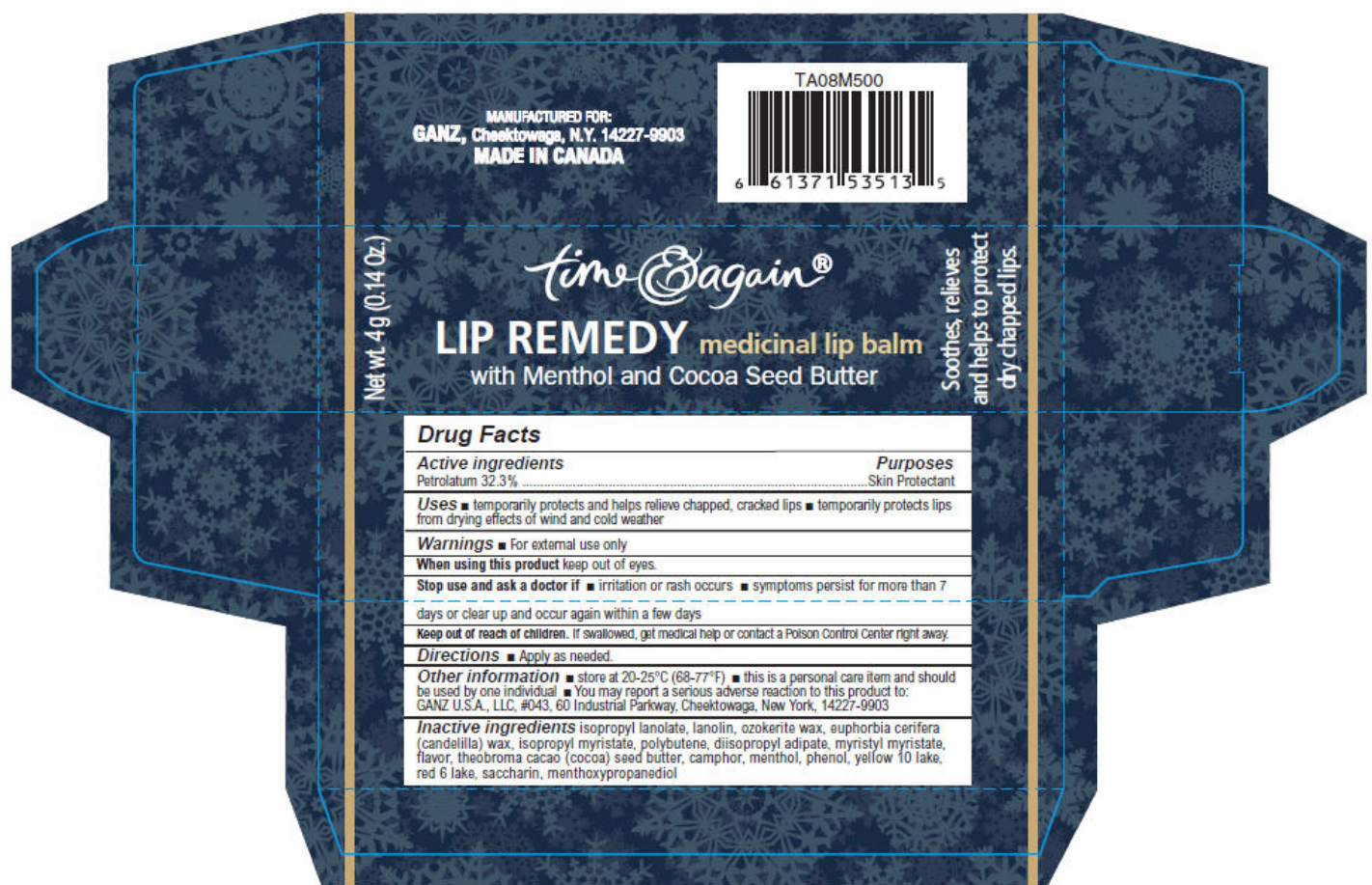
PRINCIPAL DISPLAY PANEL - 4 g Blue Carton

Net wt. 4 g (0.14 Oz.)

time & again[®]

LIP REMEDY medicinal lip balm
with Menthol and Cocoa Seed Butter

Soothes, relieves
and helps to protect
dry chapped lips.



PRINCIPAL DISPLAY PANEL - 4 g Green Carton

Net wt. 4 g (0.14 Oz.)

time & again[®]

LIP REMEDY medicinal lip balm
with Menthol and Cocoa Seed Butter

Soothes, relieves
and helps to protect
dry chapped lips.



PRINCIPAL DISPLAY PANEL - 4 g Red Carton

Net wt. 4 g (0.14 Oz.)

time & again[®]

LIP REMEDY medicinal lip balm
with Menthol and Cocoa Seed Butter

Soothes, relieves
and helps to protect
dry chapped lips.



LIP REMEDY MEDICINAL LIP BALM BLUE

petrolatum stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75862-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9 U) (PETROLATUM - UNII:4T6H12BN9 U)	PETROLATUM	32.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
CERESIN (UNII: Q1LS2UJO3A)	
CANDELILLA WAX (UNII: WL0328HX19)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	

MENTHOL (UNII: L7T10EP3A)	
PHENOL (UNII: 339NCG44TV)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
D&C RED NO. 6 (UNII: 481744AI4O)	
ALUMINUM OXIDE (UNII: LM26O6933)	
SACCHARIN (UNII: FST467XS7D)	

Product Characteristics

Color	YELLOW (BRIGHT YELLOW TO REDDISH GOLD)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75862-012-50	1 in 1 BOX		
1		4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part346	02/01/2011	

LIP REMEDY MEDICINAL LIP BALM GREEN

petrolatum stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75862-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	32.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
CERESIN (UNII: Q1LS2UJO3A)	
CANDELILLA WAX (UNII: WL0328HX19)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	

COCOA BUTTER (UNII: 512OYT1CRR)
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)
MENTHOL (UNII: L7T10EIP3A)
PHENOL (UNII: 339NCG44TV)
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)
D&C RED NO. 6 (UNII: 481744AI4O)
ALUMINUM OXIDE (UNII: LM26O6933)
SACCHARIN (UNII: FST467XS7D)

Product Characteristics

Color	YELLOW (BRIGHT YELLOW TO REDDISH GOLD)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75862-013-50	1 in 1 BOX		
1		4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part346	02/01/2011	

LIP REMEDY MEDICINAL LIP BALM RED

petrolatum stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75862-014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	32.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
CERESIN (UNII: Q1LS2UJO3A)	
CANDELILLA WAX (UNII: WL0328HX19)	

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
MENTHOL (UNII: L7T10EIP3A)	
PHENOL (UNII: 339NCG44TV)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
D&C RED NO. 6 (UNII: 481744A14O)	
ALUMINUM OXIDE (UNII: LM26O6933)	
SACCHARIN (UNII: FST467XS7D)	

Product Characteristics

Color	YELLOW (BRIGHT YELLOW TO REDDISH GOLD)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75862-014-50	1 in 1 BOX		
1		4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part346	02/01/2011	

Labeler - GANZ U.S.A., LLC (798785242)