

**LIP REMEDY MEDICINAL LIP BALM BLUE- petrolatum stick**  
**LIP REMEDY MEDICINAL LIP BALM GREEN- petrolatum stick**  
**LIP REMEDY MEDICINAL LIP BALM RED- petrolatum stick**  
**Norwood Packaging 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.*

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**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

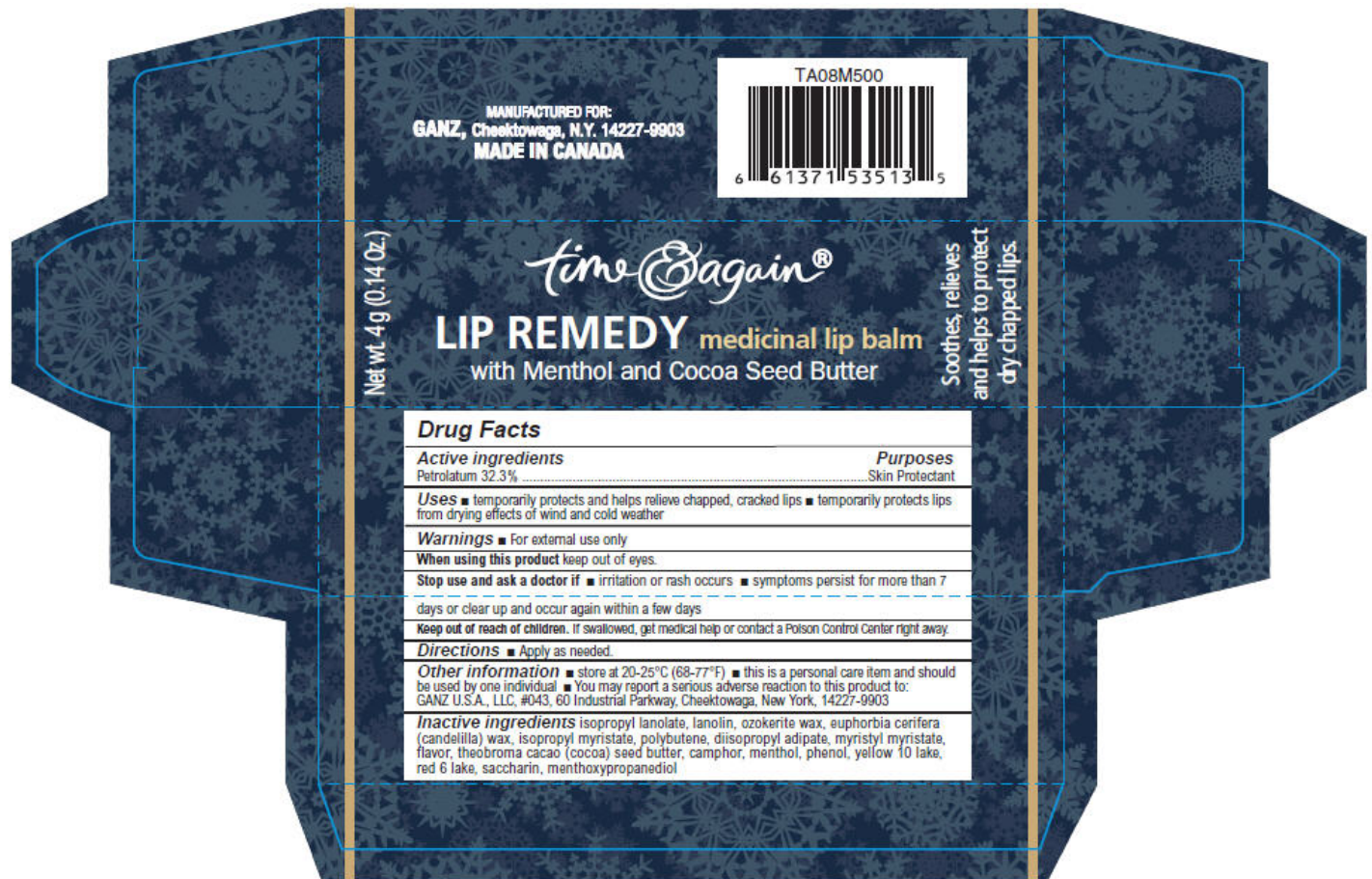
## PRINCIPAL DISPLAY PANEL - 4 g Blue Carton

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.



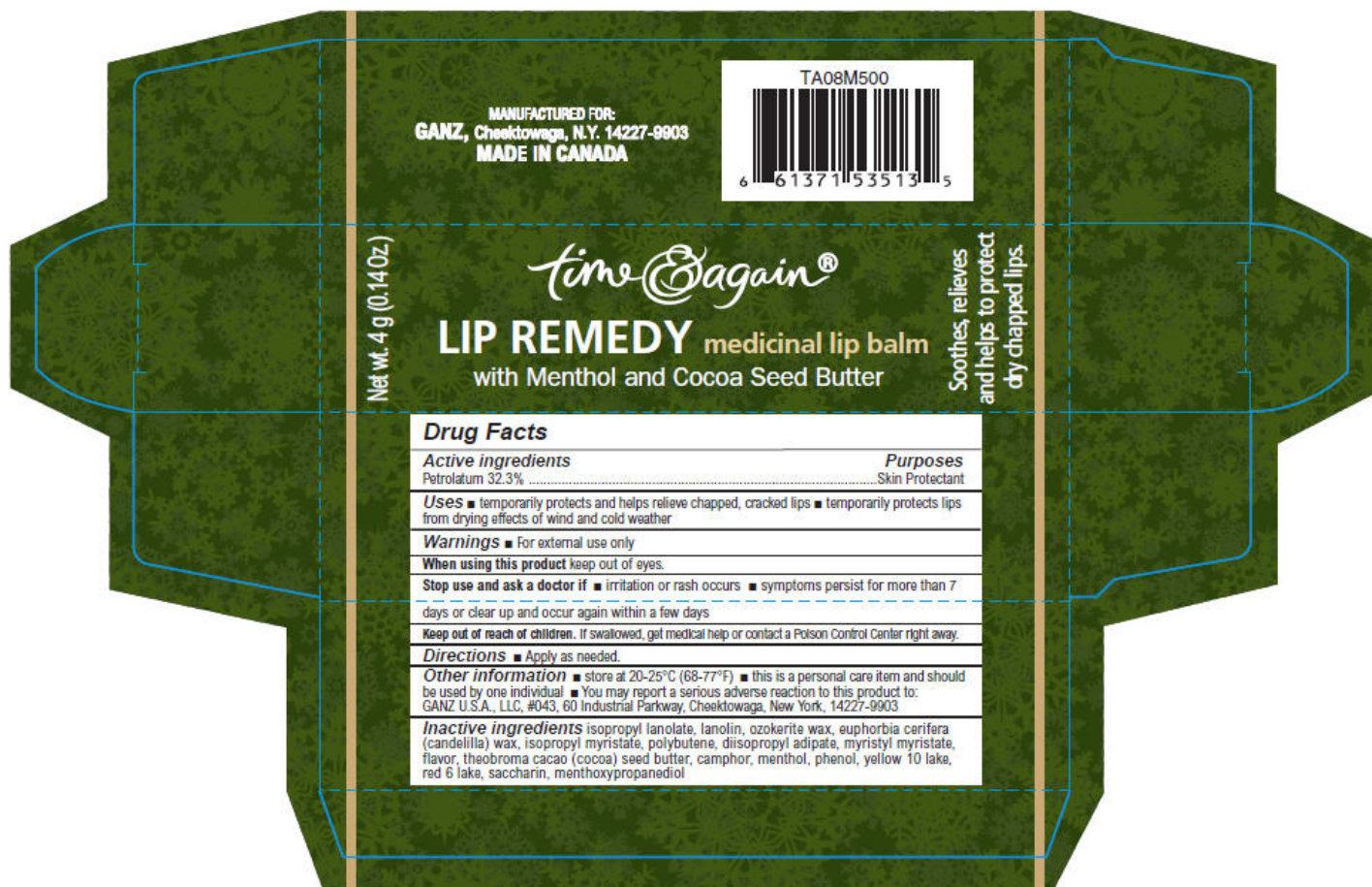
## PRINCIPAL DISPLAY PANEL - 4 g Green Carton

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*<sup>®</sup>

**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:55143-012
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:55143-012-50	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:55143-013
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:55143-013-50	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:55143-014
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:55143-014-50	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** - Norwood Packaging Ltd. (243693926)