WALGREENS PEROXIDE WHITENING- sodium monofluorophosphate paste, dentifrice Walgreens

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.

Drug Facts

Active ingredient

Sodium Monofluorophosphate 0.76% w/w (0.15% w/v fluoride ion)......Purpose: Anticavity

Uses

aids in the prevention of dental caviites

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children under 6 years of age.

Directions

Adults and children 2 years of age and older: brush teeth thorughly preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to avoid swallowing). Supervise children as necessary until capable of using without supervision.

Other Information

Store in a cool dry place. Keep tube capped when not in use.

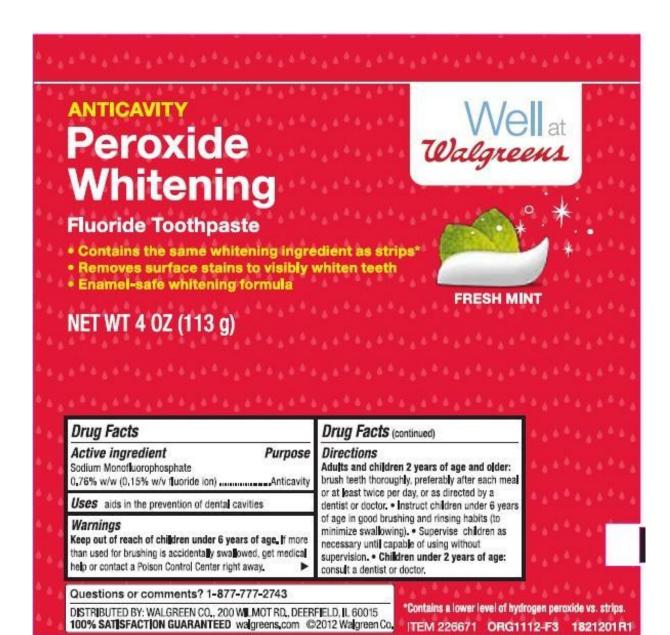
Inactive ingredients

glycerin, dicalcium phosphate, PEG-12, PVP, PEG/PPG 116/66 copolymer, hydrated silica, hydrogen peroxide, propylene glycol, flavor, sodium lauryl sulfate, tetrasodium pyrophosphate, sodium saccharin, phosphoric acid, sucralose, butylated hydroxytoluene, water

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WALGREENS PEROXIDE WHITENING

fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0363-8201
Route of Administration	DENTAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SO DIUM MONO FLUO RO PHO SPHATE (FLUO RIDE ION)	FLUORIDE ION	0.76 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN		
SO DIUM PYRO PHO SPHATE		
POLYETHYLENE GLYCOL 600		
PROPYLENE GLYCOL		
SACCHARIN SO DIUM		
SUCRALOSE		
BUTYLATED HYDRO XYTO LUENE		
PEG/PPG-116/66 COPOLYMER		
PHO SPHO RIC ACID		
HYDRATED SILICA		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT (L Menthol)	Imprint Code	
Contains			

Pa	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-8201-19	1 in 1 CARTON		
1	NDC:0363-8201-12	113 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/01/2012	

Labeler - Walgreens (008965063)

Registrant - Lornamead (126440440)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(0363-8201), pack(0363-8201)

Revised: 11/2012 Walgreens