BLANX WHITE SHOCK- sodium monofluorophosphate hydroxyapatite cetraria islandica paste Coswell Spa

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.

BlanX White Shock

ACTIVE INGREDIENT

SODIUM MONOFLUOROPHOSPHATE

INACTIVE INGREDIENTS

CETRARIA ISLANDICA EXTRACT

AQUA

HYDROXYPATITE

SORBITOL

HYDRATED SILICA

GLYCERIN

SILICA

ISOPROPYL ALCOHOL

SODIUM LAURYL SULFATE

CELLULOSE GUM

AROMA

CI 77891

SODIUM SACCHARIN

PVM/MA COPOLYMER

SODIUM BENZOATE

BENZYL ALCOHOL

PHENOXYETHANOL

CI 42090

Naturally whitens and removes
bacteria that cause plaque and tooth decay

Keep out of reach of children

For best results use twice a day

For best results apply twice a day

WARNING..DO NOT SWALLOW

BLANX WHITE SHOCK

sodium monofluorophosphate hydroxyapatite cetraria islandica paste

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70781-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.82 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
BUTYL ESTER OF METHYL VINYL ETHER/MALEIC ANHYDRIDE COPOLYMER (125000 MW) (UNII: 389H2R62BD)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETRARIA ISLANDICA SUBSP. ISLANDICA (UNII: BJ7YPN79A1)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	

Product Characteristics

Color	blue (CI 42090)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70781-002-01	75 g in 1 TUBE; Type 0: Not a Combination Product	08/26/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/14/2016	

Labeler - Coswell Spa (429512304)

Establishment

Name	Address	ID/FEI	Business Operations
Incos Cosmeceutica Industriale Srl		434933032	manufacture(70781-002)

Revised: 2/2019 Coswell Spa