DOCTOR EL BLACK WHITE TOOTH- sodium monofluorophosphate paste, dentifrice
Dr. EL CO., 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.

SODIUM MONOFLUOROPHOSPHATE

For dental care

Keep out of reach of children

Supervise children as necessary until capable of using without Supervision.

Adults and children 6 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician

Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)

Children under 2 years: Ask a dentist or physician

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

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

Sorbitol, Water, Hydrated Silica, Silica, Glycerin, Flavor, Sodium Citrate,

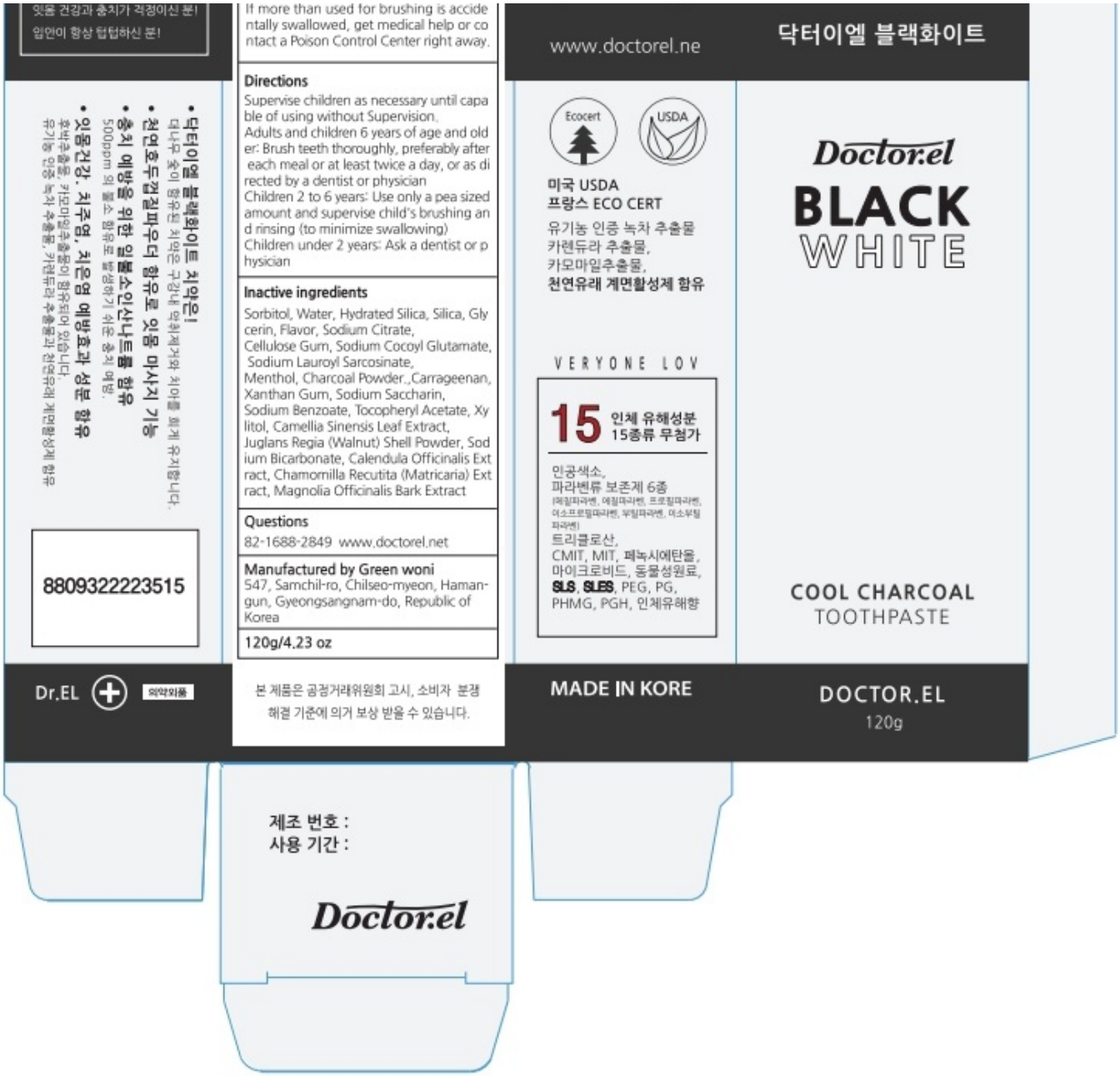
Cellulose Gum, Sodium Cocoyl Glutamate, Sodium Lauroyl Sarcosinate,

Menthol, Charcoal Powder.,Carrageenan, Xanthan Gum, Sodium Saccharin,

Sodium Benzoate, Tocopheryl Acetate, Xylitol, Camellia Sinensis Leaf Extract,

Juglans Regia (Walnut) Shell Powder, Sodium Bicarbonate, Calendula Officinalis Extract, Chamomilla Recutita (Matricaria) Extract, Magnolia Officinalis Bark Extract

For dental use only



DOCTOR EL BLACK WHITE TOOTH

sodium monofluorophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72440-110
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.38 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72440-110-01	120 g in 1 TUBE; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/01/2020	

Labeler - Dr. EL CO., LTD. (694771074)

Registrant - Dr. EL CO., LTD. (694771074)

Establishment

Name	Address	ID/FEI	Business Operations
GREEN WONIL CO., LTD.		688442099	manufacture(72440-110)

Establishment

Name	Address	ID/FEI	Business Operations
Dr. EL CO., LTD.		694771074	label(72440-110)

Revised: 7/2020 Dr. EL CO., LTD.