

TEETHWHITENING KIT- teethwhitening kit cream
Jiangxi Dentalbright Technology Co., Ltd.

Phthalimidoperoxycaproic Acid(PAP)
Potassium Citrate
Hydroxyapatite

Teeth whitening, anti-sensitivity, remineralization

Don't swallow. Avoid applying gel on the gum and lips.

Stop treatment when feel severe pain

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Keep out of reach of children.

1. Dry your teeth and rinse mouthpiece before use.
2. Looking in the mirror to record which stage you are with shade guide paper.
3. Twist whitening pen until the gel flows. apply the gel evenly on both upper and lower teeth. Each time use about 0.5-0.7ml.
4. Put mouthpiece into your mouth and bite it, then press power button for 1.5 seconds to start the treatment. (Tips: start with blue color, press again to turn red within 5 seconds; double press to turn red and blue within 5 seconds.)
5. The led light will turn off automatically after 16 minutes, rinse the mouthpiece and mouth with water and compare your teeth with shade guide paper again to see how many stages you have improved.
6. Don't eat or drink anything except water in 30 minutes after treatment.

Glycerin □ Aqua □ Polyvinylpyrrolidone(PVP) □ Ammonium
Acryloyldimethyltaurate/VP Copolymer □ Potassium Hydroxide □ Mentha Piperita
(peppermint) oil □ Mica □ Titanium Dioxide □ Saccharin Sodium □ Piroctone Olamine
PRINCIPAL DISPLAY

Don't swallow. Avoid applying gel on the gum and lips. Avoid sunlight and keep in dry & cool place

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83778-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM CITRATE (UNII: EE90ONI6FF) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	POTASSIUM CITRATE	3 g in 100 mL
PHTHALIMIDOPEROXYCAPROIC ACID (UNII: 50EJ6FAL6C) (PHTHALIMIDOPEROXYCAPROIC ACID - UNII:50EJ6FAL6C)	PHTHALIMIDOPEROXYCAPROIC ACID	12 g in 100 mL
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (PHOSPHATE ION - UNII:NK08V8K8HR)	TRIBASIC CALCIUM PHOSPHATE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)
PVP (UNII: FZ989GH94E)
GLYCERIN (UNII: PDC6A3C0OX)
PEPPERMINT OIL (UNII: AV092KU4JH)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
MICA (UNII: V8A1AW0880)
AQUA (UNII: 059QF0K00R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83778-012-01	6 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	12/14/2024	

Labeler - Jiangxi Dentalbright Technology Co., Ltd. (544503502)

Revised: 12/2024

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