

TEETH WHITENING KIT- teeth whitening kit cream
Jiangxi Dentalbright Technology Co., Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

83778-002 Update

Active Ingredient

Phthalimidoperoxycaproic Acid(PAP)
Potassium Citrate
Hydroxyapatite

Purpose

Teeth whitening, anti-sensitivity, remineralization

Use

Teeth stains from coffee, tobacco, genetic, tetracycline, food coloring, aging and other factors that may cause discoloration.

Warnings

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

Do not use

1. Not suitable for ceramic or false teeth.
2. Not suitable for teeth discoloration caused by lesion or medicine.
3. Not suitable for severe tetracycline and decayed teeth.
4. Not suitable for defective enamel, exerted dentin and damaged teeth.
5. Not suitable for children under 16 years old

When Using

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

Stop Use

Stop treatment when feel severe pain

Ask Doctor

Seek doctor's advice prior to use if pregnant, breast-feeding, having gum problem or had an oral operation recently

Keep Out Of Reach Of Children

Keep out of reach of children.

Directions

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.

Other information

Other information

Avoid sunlight and keep in dry & cool place

Inactive ingredients

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

PRINCIPAL DISPLAY PANEL



尺寸: 170*100*50mm
 工艺: 正面图案UV
 正面logo文字
 侧面文字铺射
 备注:

审核签字

TEETH WHITENING KIT

teeth whitening kit cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83778-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POVIDONE (UNII: FZ989GH94E)	

POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MICA (UNII: V8A1AW0880)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	
SODIUM ACRYLOYLDIMETHYLTAURATE (UNII: 2T9Q6EKI0G)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83778-002-01	6 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/05/2023	

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

Establishment

Name	Address	ID/FEI	Business Operations
Jiangxi Dentalbright Technology Co., Ltd		544503502	manufacture(83778-002)

Revised: 12/2024

Jiangxi Dentalbright Technology Co., Ltd