

**TEETH WHITENING KIT- teeth whitening kit cream**  
**Nanchang Dental Bright 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.*

-----

**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**

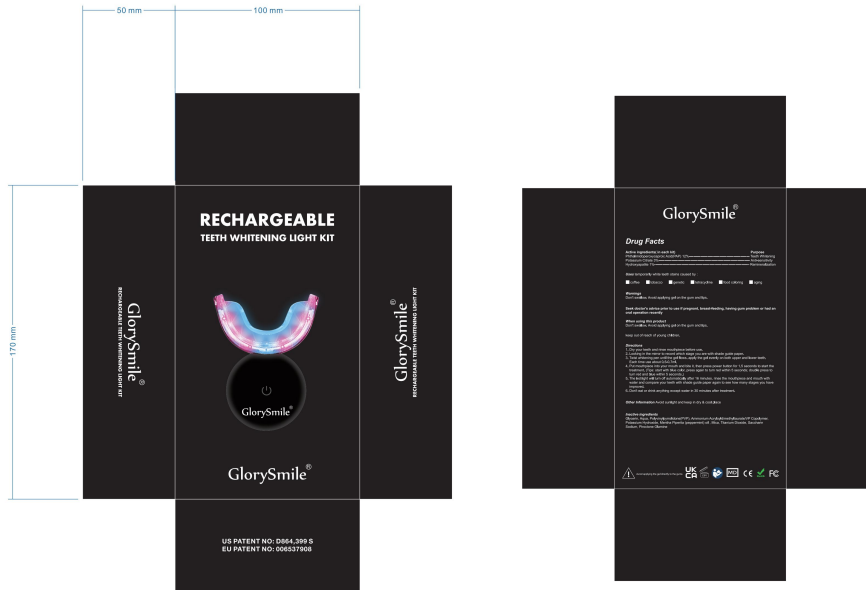
### **Other information**

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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28) (PHOSPHATE ION - UNII:NK08V8K8HR)	TRIBASIC CALCIUM PHOSPHATE	1 g in 100 mL
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	POTASSIUM CITRATE	3 g in 100 mL
<b>PHTHALIMIDOPEROXYCAPROIC ACID</b> (UNII: 5OEJ6FAL6C) (PHTHALIMIDOPEROXYCAPROIC ACID - UNII:5OEJ6FAL6C)	PHTHALIMIDOPEROXYCAPROIC ACID	12 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	

<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>PIROCTONE OLAMINE</b> (UNII: A4V5C6R9FB)	
<b>SODIUM ACRYLOYLDIMETHYLTAURATE</b> (UNII: 2T9Q6EKI0G)	
<b>GLYCERIN</b> (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** - Nanchang Dental Bright Technology Co.,Ltd. (544503502)

### Establishment

Name	Address	ID/FEI	Business Operations
Nanchang Dental Bright Technology Co.,Ltd.		544503502	label(83778-002) , manufacture(83778-002)

Revised: 11/2023

Nanchang Dental Bright Technology Co.,Ltd.