

**TEETH WHITENING STRIPS- teeth whitening strips patch**  
**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.*

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**Active Ingredient**

Phthalimidoperoxycaproic Acid(PAP)

**Purpose**

Teeth Whitening

**Use**

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

**Warnings**

1. Not intended for children under 16.
2. Do not swallow strip.
3. Avoid contact of strips with eyes or skin.
4. If the strip comes into contact with skin, it may cause temporary skin irritation.
5. If there is any discomfort, please stop using and consult a dentist immediately
6. Not suitable for people who have ulcers, exposed gums or after oral surgery.

**Do not use**

Not intended for children under 16.  
Not suitable for people who have ulcers, exposed gums or after oral surgery.

**When Using**

1. Avoid using strips after brushing your teeth. Allow at least one hour after brushing teeth before using the strips.
2. Do not re-use the strips, please dispose of once used.
3. The ingredients of the strips are safe and if some gel is swallowed, it is perfectly safe.
4. Clean off any remaining gel residue by brushing your teeth and gargling.

**Stop Use**

If there is any discomfort, please stop using.

## **Ask Doctor**

If there is any discomfort, please consult a dentist immediately

## **Keep Out Of Reach Of Children**

keep out of reach of young children

## **Directions**

1. Remove strips from backer.
2. Apply upper strip to top teeth, and repeat with bottom teeth.
3. Leave for 30 minutes, avoid eating or drinking.
4. Remove and discard strips, rinse away any existing gel and admire.

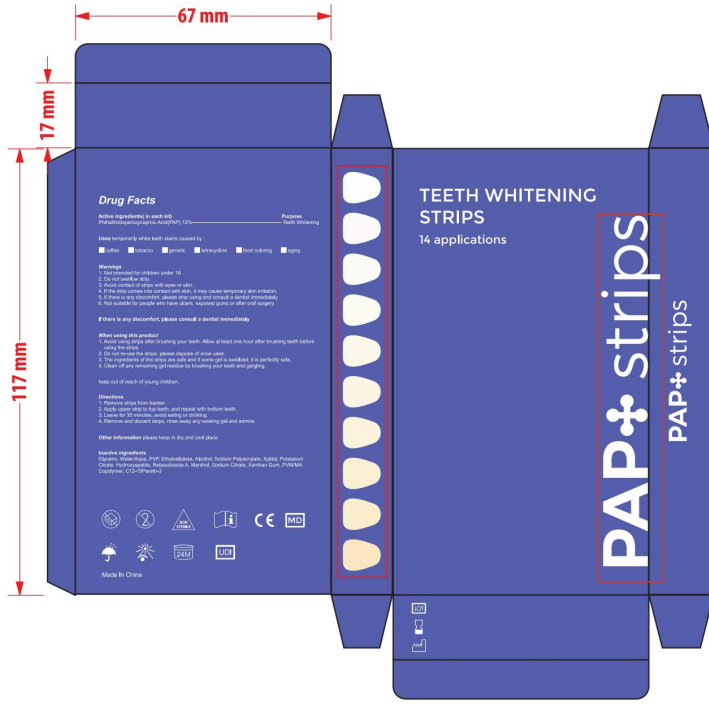
## **Other information**

please keep in dry and cool place

## **Inactive ingredients**

Glycerin □ Water/Aqua □ PVP □ Ethylcellulose □ Alcohol □ Sodium Polyacrylate □ Xylitol □ Potassium Citrate □ Hydroxyapatite □ Rebaudioside A □ Menthol □ Sodium Citrate □ Xanthan Gum □ PVM/MA Copolymer □ C12-15Pareth-3

## **PACKAGE/LABEL PRINCIPAL DISPLAY PANEL**



尺寸: 117\*67\*17mm  
工艺: 哑膜 红框中UV

红框中UV

审核签字

## TEETH WHITENING STRIPS

teeth whitening strips patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83778-003
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHTHALIMIDOPEROXYCAPROIC ACID</b> (UNII: 5OEJ6FAL6C) (PHTHALIMIDOPEROXYCAPROIC ACID - UNII:5OEJ6FAL6C)	PHTHALIMIDOPEROXYCAPROIC ACID	12 g in 100

### Inactive Ingredients

Ingredient Name	Strength
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28)	
<b>METHYL VINYL ETHER AND MALEIC ANHYDRIDE COPOLYMER (110000 WAMW)</b> (UNII: T0VRI38HB0)	
<b>C12-15 PARETH-3</b> (UNII: 459EF9MP3Y)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	

<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>REBAUDIOSIDE A</b> (UNII: B3FUD0528F)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>ETHYLCELLULOSES</b> (UNII: 7Z8S9VYZ4B)	
<b>SODIUM POLYACRYLATE (2500000 MW)</b> (UNII: 05I15JN12J)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83778-003-01	14 in 1 BOX; 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(83778-003) , manufacture(83778-003)

Revised: 11/2023

Nanchang Dental Bright Technology Co.,Ltd.