



FDA ADVISORY
No. **2020-054**

23 JAN 2020

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Unregistered Medical Device “Whiter Smile Home Teeth Whitening Kit”

The Food and Drug Administration (FDA) warns all healthcare professionals and the general public against the purchase and use of the unregistered medical device:



Figure 1. Unregistered Whiter Smile Home Teeth Whitening Kit



HOME TEETH WHITENING KIT

User Manual

Step 1: Molding



Mould the thermoplastic mouth trays

- Submerge the mouth trays in boiling water for 5 seconds. You will see it soften a bit.

BE CAREFUL NOT TO OVERHEAT AS THE TRAYS MAY SHRINK.

- Bite down tray ASAP to form an impression. It will not burn you do not worry. Practice sucking the air from the tray, this will contour the tray to form your teeth structure.



*Repeat procedure if necessary.

Step 2: Trim



Trim the formed mouth trays

- To avoid gel contact with the soft tissues (gums), trim the trays on the teeth and gum line using scissors.

Step 3: LED Light



Turning On the light

- Twist battery cover counter clockwise. Pull and remove cover. Remove transparent tab, and then insert both batteries '+' side up. Replace battery cover and turn clockwise to close.

Step 4: Whiten



Fill mouth trays & whiten teeth

- Fill the trays with gel along the inner corner of the teeth trays covering about 6-8 teeth.
- Be careful not to overload the tray to avoid contact with gums. Less is best.
- 1ml or less for both upper and lower teeth should be enough.
- Place the upper and lower trays into your mouth, & adjust accordingly.
- Turn on LED light provided by pressing the white button. Then hold the light as close to your teeth as possible. This will accelerate treatment.
- For first time users, we recommend that you do a 20 minute treatment. (up to 1hr if teeth are not sensitive)

Ingredients:

(Carbamide Peroxide Whitening Gel)
 Propylene Glycol, Glycerine, Carbamide Peroxide, Carbopol, Peppermint Flavour, Mica/ Titanium Dioxide, Trielamine, Sucralose, Ferrous Gluconate



Range of Application:

Teeth stain from coffee, tobacco, genetic cause, tetracycline, food coloring, aging and other kinds that cause yellow teeth.

Storage:

Avoid sunlight and keep in cool area.

Shelf Life: 12 Months

AGREEMENT:

By purchasing this product you agree that you are 18 or over. You do not have overly sensitive teeth. (We have lower carbamide peroxide percentage for sensitive teeth if needed.) The product will only be used to whiten your teeth. Your teeth are not decayed or loose. Whitening products will not whiten any existing dental restorations such as fillings, crowns, veneers, bridges, etc. It may help remove surface stains only. You will not use the whitening products if you are pregnant or lactating, have braces, have jaw problems, have exposed roots, have health problems, etc. You are not allergic to the ingredients listed. *Liability is limited to cost and amount of this product only.

IMPORTANT NOTE:

Molding and cutting the trays customized to your teeth is the most important step. This gel will only work with nicely fit trays. Poorly molded trays will burn your gums. As a result the gel will not whiten and your gums will hurt. If you burn your gums, it will turn white. Rinse out ASAP. The burning feeling will go away after 24-48 hrs.

Whiter Smile

Figure 2. Brochure of the unregistered Whiter Smile Home Teeth Whitening Kit

The FDA verified through post-marketing surveillance that the abovementioned medical device is not registered and the Certificate of Product Registration (CPR) has not yet been issued. Pursuant to the Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Since this unregistered medical device has not gone through evaluation process of the FDA, the agency cannot assure its quality and safety.

In light of the foregoing, the public is advised not to purchase the violative product in the market.

All concerned establishments are warned not to distribute, advertise, or sell the said violative medical device until CPR is issued, otherwise, regulatory actions and sanctions shall be strictly pursued.

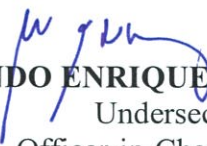
All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to ensure that this product is not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of this unregistered product.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at cdrrhr@fda.gov.ph, or call (02) 857-1900 loc. 8301.

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport** can be accessed at www.fda.gov.ph/ereport.

Dissemination of this advisory to all concerned is hereby requested.


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