## CAITHEC Indústria e Comércio Ltda.



Technical person responsible: Larissa Christine Tuffi – CRF/PR 31.039

Anvisa Notification No. 80403360021

## INSTRUCTIONS FOR USE

# WHITEChome HOME BLEACHING

#### 1. PRODUCT DESCRIPTION

WHITEChome Home Bleaching is a product developed for the whitening of vital teeth, for home use. With concentrations of 10%, 16% and 22% of carbamide peroxide, tooth whitening is effective, since carbamide peroxide is decomposed into hydrogen peroxide penetrating the teeth pores and oxidizing the pigments responsible for darkening. High viscosity carbomer gel ensures precise application, preventing leaks from the whitening tray. With a neutral pH, WHITEChome Home Bleaching does not cause enamel and dentin decalcification. Its formula contains humectants and a high water content to prevent dental dehydration. This product features a combination of potassium nitrate and sodium fluoride as desensitizing agents, minimizing tooth sensitivity as much as possible during the bleaching process.

#### 2. PRESENTATION

Syringe containing 3g of WHITEChome Home Bleaching at 10%, 16% or 22% concentrations.

#### 3. COMPOSITION

Carbamide peroxide, neutralizing agent, thickener, remineralizer, structurer, desensitizing agents and purified water.

## 4. INDICATION OF USE

WHITEChome Home Bleaching is indicated for home use, following the dental whitening technique supervised by the dentist. It is effective in whitening vital teeth, removing stains caused by congenital, systemic, pharmacological, traumatic and age-related factors. It offers excellent results in the treatment of spots resulting from fluorosis, especially brown spots. It is also recommended for first and second degree tetracycline stains

WHITEChome Home Bleaching with 10% concentration is indicated for natural stains related to age, smoking or in case of greater tooth sensitivity. Concentrations of 16% and 22% are recommended for older and more pronounced stains, which are challenging to remove, or when you are looking for faster results.

### 5. ACTION

The WHITEChome Home Bleaching has the action of the whitening agents penetrating the dental structures and their reaction with the pigmented molecules, oxidizing and fractionating into smaller and smaller molecular chains, causing the pigments incorporated to the tissues to be totally or partially eliminated from the dental structure by diffusion.

### 6. CONSERVATION/STORAGE

- Keep the product in its original packaging always closed.
- Protect it from direct sunlight.
- Store the product at temperatures between 5°C and 28°C.
- And do not freeze the product or leave it exposed to high temperatures.

#### 7. INSTRUCTIONS FOR USE

Initially, it is recommended that a professional dentist perform the prophylaxis and record the color of the patient's teeth, using photographs or a Vitta color scale. Before each application of the product, a complete and effective hygiene of the teeth should be done with a brush and dental floss, avoiding aggressive brushing on the gums. Food residues can compromise the whitening result.

a. Once the WHITEC tray has been prepared and cleaned, remove the syringe cap and attach the applicator tip to place one to three drops of WHITEChome bleaching gel in each compartment of the tray for the teeth to be whitened.

b. After that, the WHITEC tray should be positioned in the mouth, so that the teeth come into contact with the gel. Any excess gel should be removed.

c. Take the WHITEC trays to the mouth one by one and press them with the thumb and forefinger against the teeth so that the gel spreads and covers all of them.

d. Remove excess gel with your index finger. After using the WHITEC tray filled with gel for the recommended time (from  $\frac{1}{2}$  hour to 2 hours daily, or the time recommended by the dentist), remove the WHITEC tray.

e. Clean the WHITEC tray using a toothbrush and running water. Dry and store the WHITEC tray in a suitable place. f. Rinse your mouth with water and, if necessary, brush your teeth again.

g. After removing the WHITEC tray, it should be carefully cleaned and stored with the opening of the teeth compartments facing downwards, so as not to retain water. This product can be used during the day, as long as it is not immediately followed by a meal. In this case, the product must remain in contact with the teeth between 1 and 2 hours. Another option is to let it act during sleep, a period of approximately 8 hours. In both cases, continuous use of the whitening gel between 15 and 21 days is recommended, with supervision by the dentist. Special care must be taken not to chew or ingest while the tray is in the mouth.

#### 8. CONTRAINDICATIONS

• Do not use the liquid alone.



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- This is a product that must always be indicated and supervised by a dentist.
- Before starting treatment, inform your patient about the possibility of tooth sensitivity.
- The product should not be used by pregnant and/or breastfeeding women and in patients under 14 years of age.
- Avoid intentional and excessive ingestion of the product.
- Do not use on patients with any sensitivity to the components of this product. Patients with a history of allergies to the components of this formulation should consult a specialist before starting treatment.
- Avoid smoking during the treatment period and do not smoke immediately after removing the tray.
- During treatment, the patient should avoid ingestion of drinks, fruits and acidic products, thus avoiding sensitivity.
- During treatment, avoid consuming products that contain strong dyes such as: coffee, chocolate, soft drinks, wine, beets, among others, in order not to compromise the bleaching process.
- Advise your patient to return to the office to follow up the treatment after a week (7 days), in order to evaluate and guarantee the effectiveness of the dental bleaching results until the end of the treatment.
- If any problem occurs, interrupt treatment and tell your dentist.
- If a large volume of product is accidentally swallowed, seek medical attention.
- Non-injectable product. Do not reuse packaging.

#### 9. ADVERSE EFFECTS

- Ingestion of large amounts of the product may
  cause pausea.
- Before starting treatment, inform your patient about the possibility of tooth sensitivity. Dental sensitivity is usually common during bleaching treatment.
- In this case, if sensitivity persists, treat the teeth with SENSITEC 0.2% Desensitizing Gel indicated for moderate to low sensitivity or SENSITEC 2% Desensitizing Gel indicated for moderate to high sensitivity.

 Excess gel in the tray can cause slight irritation to the gingival tissue, so always remove the excess according to the patient's instruction manual.

#### 10. SPECIAL CARE

• Suspend the use of the product in case of allergic reactions.

#### 11. MANIPULATION

• Aseptic environment.

#### 12. INTERACTIONS

No interactions.



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