TEETH WHITENING KIT - BIANCA PRO - WHITEN PRO

(In-Office Whitening System — 35% Hydrogen Peroxide)

INSTRUCTIONS FOR USE (Please read carefully before use)

Doc. No: **HH/IFU/16** Approved By: **Mr. Vikram Vora** Language: **English**

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PRODUCT DESCRIPTION: Teeth Whitening Kit is a hydrogen peroxide based rapid, in-office tooth whitening system, supplied in two formats. In the powder–liquid format, liquid and thickener are mixed together to form a freshly activated gel. In the gel format, two syringes are joined with a connector and the contents mixed between the syringes to form the activated gel. In both formats the freshly activated gel is applied on the teeth with a fine applicator tip or brush. The kit includes gingival barriers with precision tips for protection of the gums during treatment.

MATERIAL OF CONSTRUCTION: Liquid / first syringe contains — 35% hydrogen peroxide and excipients. Thickener / second syringe contains — fillers and desensitizing agents. Gingival barrier contains — urethane dimethacrylate, triethylene glycol dimethacrylate, fillers, radiopacifier, photoinitiator and stabilizer.

INDICATIONS: Assists in whitening of discoloured teeth related to medication, age dependent changes and food related stains.

INTENDED USE: It is intended to be used for tooth whitening. For professional use only.

WORKING TIME: Use the mixed gel within 30–40 minutes after mixing. Leave each application on the teeth for 10 minutes.

PROCEDURE & PRODUCT HANDLING:

- Determine the pre operative shade for comparison after whitening.
- Clean the teeth with pumice.
- Place cheek retractors and then cover exposed lip surface with petroleum jelly.
- Dry teeth and apply the gingival barrier to both arches, slightly over lapping enamel and interproximal spaces. Light cure in a fanning motion for 20–30 sec until it is cured.

MIXING — POWDER–LIQUID FORMAT:

- Open the thickener pot and carefully empty the liquid into the pot. Mix thickener and liquid with a brush to form a homogeneous gel.

MIXING — GEL FORMAT:

- Remove the caps from both syringes and join them with the mixing connector, ensuring the connection is secure.
- Transfer the contents from one syringe to the other repeatedly until a homogeneous gel is obtained, then collect the mixed gel in one syringe, remove the connector and fit an applicator tip.
- Apply a thick layer of gel to all teeth undergoing treatment and leave the gel for 10 minutes. Suction off saliva using an aspiration tip.
- Repeat the procedure 2–3 times using mixed gel. Use the mixed gel within 30–40 minutes after mixing.
- After the last application, suction all the gel, then wash and apply suction.
- Remove the gingival barrier by lifting it from one end.
- The dispensed material shall not be placed back in the container and the dose once applied and used shall not be reused.

CAUTION / WARNING:

1. Device to be used by a qualified dentist or dental technician only.
2. Products containing peroxide are not recommended for use by children under 12 years of age.
3. Avoid prolonged or repeated contact with skin (allergic contact dermatitis) and eyes. Avoid prolonged inhalation. Do not take internally. Contact with the skin may cause irritation or burns of hypersensitivity. If contact with skin occurs, immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs, discontinue use and seek medical attention.
4. If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician. It should not be used with patients who have a history of severe allergic reaction to any of the components.

PRECAUTIONS:

1. For professional use only.
2. Patient must wear protective eyewear.
3. Professional must wear gloves, mask and protective eyewear.
4. Do not use on pregnant or lactating women and children below the age of 15 years.
5. Do not use on any person having known peroxide allergies.
6. Handle the liquid bottles carefully as the same may be pressurized.
7. Do not allow mixed gel or liquid to come in contact with skin, eye and soft tissues.

CONTRAINDICATIONS:

1. Do not use in patients with unknown history of allergy to any of its components.
2. Do not use in pregnant or lactating women.

INTERACTIONS WITH OTHER DENTAL MATERIALS: Kindly communicate and inform the manufacturer with complete details in case of any incidences of interaction.

ADVERSE REACTIONS: Contact with the skin may cause irritation, burns of hypersensitivity or allergic contact dermatitis. If skin rash, sensitization or other allergic reaction occurs, discontinue use and seek medical attention. Kindly communicate and inform the manufacturer in details of any instance.

PACKAGING: Powder–liquid format — 5 × gingival barriers with precision tips, 2 × bottles of 35% hydrogen peroxide, 5 × applicator tips, 1 × 5 g thickener for gelation. Gel format — 2 × syringes with mixing connector, gingival barriers with precision tips and applicator tips.

STORAGE CONDITIONS: Store at a temperature between 10°C (50°F) to 24°C (75°F). Close the cap carefully after use. Keep away from moisture and direct sunlight. Keep locked up and out of the reach of children. Shelf life not affected after opening if stored in a cool dry place.

SHELF LIFE: 3 years from the date of manufacturing.

DISPOSAL: To be disposed off based on the prevailing rules of the country in which it is used.

This product is specially formulated for use in dentistry and to be used by qualified dental personnel.

LOT Symbol for “BATCH CODE”

Symbol for “KEEP DRY”

REF Symbol for “CATALOGUE NUMBER”

Symbol for “DO NOT USE IF PACKAGE IS DAMAGED”

MD Symbol for “MEDICAL DEVICE”

Symbol for “USE BY”

Symbol for “CAUTION”

Symbol for “KEEP OUT OF THE REACH OF CHILDREN”

Symbol for “TEMPERATURE LIMITATION”

IN Symbol for “COUNTRY OF MANUFACTURE”

Symbol for “NON STERILE”

Symbol for “CONSULT INSTRUCTIONS FOR USE”

Symbol for “MANUFACTURER”

Symbol for “KEEP AWAY FROM SUNLIGHT”

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Kindly retain the instructions for use & packaging box until the complete use of the product / expiry.

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding.