

ENA WHITE 2.0

The fastest home professional bleaching

ENA CARE®
White

Instruction for Use DENTIST

ENA® WHITE 2.0 is a dentist-controlled, dentist-supervised, take-home bleaching.

It is a system made up of a special toothbrush with dispenser and a syringe which contains a clear blue, mint flavoured, high-viscosity, 6% hydrogen peroxide gel.

It is applied with the special toothbrush filled with the bleaching gel with the accelerator XS151™ which activates while brushing and allows to reduce the time of daily application to two minutes only instead of the 6/8 hours necessary with conventional bleaching systems with tray. It should not be used in case of known allergies or intolerances to either of the ingredients mentioned in the label. Mint flavour can be irritating to some patients.

INSTRUCTIONS FOR USE

Before treatment, it is wise to schedule the patient for a prophylaxis and oral hygiene visit including plaque and stain removal and enamel cleaning and polishing.

The toothbrush is composed of a dispenser to be filled with the bleaching gel contained into the syringe (enough for two refills for treatments of 20 days each).

FIRST REFILL

- 1) Store the syringe in the fridge until the first use.
- 2) When the first treatment is performed, take the syringe from the fridge and remove the small cap on the syringe tip; keep it in order to cap the syringe again (pic. 1).
- 3) After removing the cap open the toothbrush and unscrew the head from the dispenser (pic. 2).
- 4) Push the silicon disc using the syringe tip (pic. 3) until it reaches the bottom of the dispenser.
- 5) Inject the gel into the dispenser until only 5 ml of gel remain into the syringe; always leave the syringe tip into the gel in order to avoid any bubbles (pic. 4-5). Cap the syringe again and place it in the fridge.
- 6) Screw the head of the toothbrush on the dispenser (pic. 6) (the special head GUM CARE™ of reduced size limits the risk of contact with gingival tissue), rotate anti-clockwise the ring on the base of the toothbrush towards the direction "UP" until the gel is coming out from the hole between the bristles. It is necessary a dose like the volume of a small lentil (pic. 7). Instruct the patient to use the product performing the first treatment with him.

For the daily treatment the patient will have to:

- take out from the fridge the toothbrush ENA®WHITE 2.0 and unscrew the cap.
- rotate anti-clockwise the ring on the base of the toothbrush towards the direction "UP" until a quantity of gel like a small lentil is coming out (after the first application it will be sufficient to rotate the ring of 2-3 marks), then brush the teeth for about 30 seconds avoiding to brush the gums (pic. 8).
- rinse the toothbrush with water (pic. 9) and brush again the teeth for other 30 seconds (pic. 10), then rinse carefully the mouth with water as usual. NOTE: The application times indicated are sufficient for a treatment limited to the 6 upper central teeth. In case that also lower teeth must be bleached it is necessary to increase the brushing time of about 15 seconds.
- screw the cap of the toothbrush. In order to avoid gel spilling, especially during transport, slightly rotate the ring towards the direction "DOWN".
- repeat for 2-3 times per day, preferably after oral hygiene (it is recommended to use the toothpaste Enamel Plus, with low abrasion formula, desensitizing and tooth-whitening action and the IF Interdental Floss of the Eno®Oral Care line). The innovative packaging allows to perform the treatment even when not at home, in the office, at the gym using previously the Digital Brush towel to clean the teeth. After showing the treatment to the patient, the product can be delivered with the enclosed instructions.

The patient must be informed about the necessity to reduce the intake of food and beverages, which have the increased capacity to cause discolouration, the number of cigarettes and all the habits that can negatively influence the treatment efficacy. Moreover, the patient should be made aware of possible transient episodes of hypersensitivity; if these become particularly annoying, the treatment should be temporarily suspended.

SECOND REFILL

- 7) When the patient comes back for a check after 20 days, check the colour (the patient must bring the empty toothbrush). In case the patient requires further bleaching effect, proceed as follows:
- 8) Take the syringe with the remaining 5 ml from the fridge and remove the cap.
- 9) Open the patient's toothbrush after removing the cap and unscrew the head from the dispenser. Rotate the ring towards the direction "DOWN" until the piston reaches the bottom of the dispenser (pic. 11).
- 10) Push the silicon disc of the dispenser using the syringe tip (pic. 12) until it reaches the bottom of the dispenser (pic. 13).
- 11) Inject the gel into the dispenser until the content of the syringe finishes; always leave the syringe tip into the gel in order to avoid any bubbles (pic. 14).
- 12) Screw the same head (which contains the residual gel) on the dispenser and give the toothbrush back to the patient.

NOTE: In case the patient does not need further bleaching, the remaining refill of 5 ml can be used for the same patient later, or for another patient for a third treatment of 20 days; as a residual of the gel of the previous refill remains into the head, always check the expiry date indicated on the toothbrush before refilling. In order to avoid any contamination, always use a new syringe for the first refill, and a syringe which has already been opened for the second or third refill.

THE RECOMMENDED AVERAGE CYCLE OF TREATMENT IS:

1/2 minutes twice or three times a day, until finishing the dispenser contents, it is sufficient for a treatment of 2/3 weeks.

PRECAUTIONS

1. Not to be used on a person under 18 years of age.
2. To be only sold to dental practitioners. For each cycle of use, the first use to be only done by dental practitioners or under their direct supervision if an equivalent level of safety is ensured. Afterwards ENA® WHITE 2.0 can be delivered to the patient to complete the cycle of use.
3. Please note the expiration date printed on the package indicated by the hourglass symbol (month/year).
4. Avoid contact with eyes; rinse immediately for several minutes if product comes into contact with them. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice. The use of peroxide can give rise to a series of problems, the more common being dentine hypersensitivity and irritation of the mucosa; it is therefore contraindicated in the presence of certain conditions, as listed below:
 - Exposed dentine areas
 - Pregnancy
 - Presence of gingival inflammation
 - Presence of extensive caries
 - Presence of amalgam restorations in the anterior teeth (possible grey colouration caused by the chemical reaction peroxide-silver)
 - Defected filling margins
 - Dental hypersensitivity

A certain reduction in the micro-hardness of enamel, after treatment with hydrogen peroxide, has been recently observed, which nevertheless, returns to its initial condition, thanks to the remineralisation process

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commencing immediately after treatment. Topical application of a fluoride gel (ie Ena White desensitizing gel) which progressively re-mineralises the enamel is indicated to reduce the phenomenon of pulpal sensitivity. Finally, it was noted that treatments with hydrogen peroxide condition the possibility of performing an adhesive restoration, since they affect the presence of residual free radicals on the surface of the tooth and this could influence the bond strength between the adhesive system and the tooth surface. It is therefore appropriate to wait at least two weeks after the treatment is completed, before obtaining a clinically viable adhesive bond. With regards to the soft tissues, it is necessary to avoid to brush them, with the bleaching gel with the consequence of more or less acute gingival irritations, sensations of an unpleasant taste and burning of the palate (the special head GUM CARE™ of reduced size limits the risk of contact with gingival tissue). The use of peroxide in general is not recommended for a patient, who has recently had periodontal surgery, nor in handicapped patients, or in heavy smokers. If gingival or tooth discomfort persists (such as excessive temperature sensitivity), inform the patient to discontinue the treatment and make an appointment for evaluation. Maintain control of ENA® WHITE 2.0 whitening agent, dispensing one toothbrush bleaching system until next appointment. Monitor patients' bleaching progress to prevent bleaching beyond the desired level of whitening or degree of translucency. Understand each patient's expectations before beginning

treatment. Inform patients that existing crowns, tooth coloured fillings, etc., do not whiten, even though natural teeth potentially will. ENA®WHITE 2.0 is supplied to the patient into a toothbrush with dispenser containing a load of about 6 ml of bleaching gel. Once the gel has finished, if necessary the patient must bring it to the dentist for the second refill. Patients should be instructed about the disposal of the toothbrush once the treatment has been finished, as indicated in the instructions for patients. In case the whole package expires before use, it must be eliminated as a dangerous product. Keep out of heat and/or direct sunlight. Store the syringe with the bleaching gel in refrigerator at the temperature 2° - 8°C (36°-46°F). Instruct the patient to keep the toothbrush filled with the gel out of heat and/or direct sunlight and to store the product at room temperature (20°C - 68°F) during the treatment, for maximum 2-3 weeks. In case of treatment interruption store the product in the fridge. ENA®WHITE 2.0 contains hydrogen peroxide; swallowing large amounts can be harmful. The innovative application system with a toothbrush designed to optimize and accelerate the treatment prevents the patient from swallowing large gel quantities. Instruct the patient to not swallow the bleaching gel or gel rinses and to rinse carefully after use also the areas below the lips.

FIRST REFILL



Pic 1. Take the syringe out of the fridge



Pic 2. Remove the cap and unscrew the head of the toothbrush from the dispenser



Pic 3. Push the piston towards the bottom of the dispenser using the syringe tip



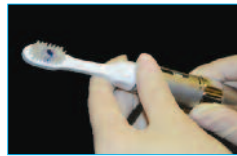
Pic 4. Fill it with the gel...



Pic 5. ...until about 5 ml of gel remain into the syringe. Place the syringe with the remaining quantity in the fridge



Pic 6. Screw the head of the toothbrush on the dispenser



Pic 7. Rotate the ring towards the direction UP until the gel is coming out from the hole between the bristles. It is necessary a dose like the volume of a small lentil



Pic 8. The patient must brush the teeth to be bleached for about 30 seconds with rotating and horizontal movements avoiding as much as possible the contact with gums



Pic 9. Rinse the toothbrush with running water

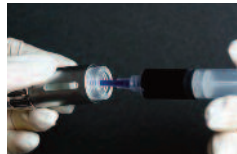


Pic 10. Brush again for other 30 sec. and rinse accurately

SECOND REFILL



Pic 11. In case further bleaching is needed, the patient must bring the toothbrush to the dentist. Remove the head (see Pic. 2) and rotate the ring towards the direction "DOWN"



Pic 12. Using the syringe tip push the piston...



Pic 13. ...towards the bottom of the dispenser



Pic 14. Fill it with the gel until the content of the syringe finishes. Screw the head (see Pic. 6) and give the toothbrush back to the patient.



GRUPPO
MICERIUM

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