

ENA WHITE 2.0

The fastest home bleaching

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 which contains a clear blue, mint flavoured, high-viscosity, 6% hydrogen peroxide gel.

It is applied with the special toothbrush containing the bleaching gel, the accelerator XS151™ 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. 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.

HOME TREATMENT

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 containing the bleaching gel. When delivering the product to the patient, the dentist must remove the cap, unscrew the head of the brush, remove the seal and screw the toothbrush again (the special head GUM CARE™ of reduced size limits the risk of contact with gingival tissue); then he must 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. 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.

- rinse the toothbrush with water and brush again the teeth for other 30 seconds, 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 Ena® 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.

THE RECOMMENDED AVERAGE CYCLE OF TREATMENT IS:

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

PRECAUTIONS

Warning! Before use, remove the seal

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
 - Dentine 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 commencing immediately after treatment. Topical application of a fluoride gel (ie Ena White desensitizing gel) which progres-

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sively 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 allow 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 on 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 hand-capped 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 into a toothbrush with dispenser containing a load of about 6 ml. The toothbrush is disposable and once the gel is finished, it must be thrown away and patients should be instructed about the disposal of the toothbrush once finished the treatment, as indicated in the instructions for patients. In case the whole package expires before use, it must be eliminated as a dangerous product. Store the toothbrush in refrigerator at the temperature 2°- 8°C (36°-46°F). Instruct patients to keep the product out of heat and/or direct sunlight and to store the product in the fridge even if it is possible to store it at room temperature (20°C - 68°F) for maximum 2-3 weeks. If the treatment is interrupted, 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.



Screw and remove the cap of the toothbrush



Unscrew the toothbrush and remove it from the dispenser



Remove the seal



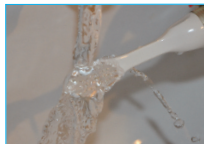
Screw the toothbrush again



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



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



Rinse the toothbrush with running water



Brush again for other 30 sec. and rinse accurately

ENA CARE®
White



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