

Easywhite® Ready

Instructions for use

English

Description:

Easywhite® Ready is a 2-component material for brightening discolored teeth. It is only intended for professional medical treatment in dental practices. The bleaching agent is activated by mixing the two components.

Duration of treatment is defined individually and depends on the sensitivity of the teeth, the desired level of whitening and the type and scope of discoloration of the teeth.

Composition:

32% hydrogen peroxide, water, glycerin, sodium-magnesium silicates, potassium phosphate, sodium phosphate, silica, polyglycols, organic amines, sodium hydroxide, potassium hydroxide, food coloring.

Indications (fields of application):

Easywhite® Ready is used for rapid, medically-indicated whitening of strongly discolored vital and devitalized teeth, whose color cannot be returned to a natural or normal tooth shade through professional tooth cleaning.

Medically-indicated whitening of teeth applies to discoloration which leads to a worsening of the (health-related) quality of life of the patient due to pronounced changes in the colour of teeth. Where appropriate, professional bleaching of teeth can also be used as an alternative to veneering the teeth concerned with veneers or crowns.

Examples for the causes of such (intrinsic) discoloration are:

- discoloration due to tetracycline / minocycline
- moderate to severe dental fluorosis (TF index > 2)
- devitalized teeth (pulp necrosis) - e.g. caused by trauma
- genetic or (degenerative) discoloration due to age
- porphyria or icterus
- Pronounced food deposits with penetration of the tooth structure (intrinsic discoloration through extrinsic dyes)

Tooth color shades usually present in the population in terms of brightness, translucency and color, are regarded as *natural* or *normal*. Aids for establishing a diagnosis or the indication include, for example, the Vita A1-D4 classical shade scale (for the most frequently occurring natural shades) and the separately available questionnaire (OHIP-G₁₃) for determining quality of life with regard to oral health.

Easywhite® Ready is used for whitening one or more teeth or parts of a tooth. It is suitable for bleaching individual, orthodontically treated devitalized teeth, including intra-coronal bleaching.

Recommendations on diagnosis:

A specially developed questionnaire for determining the oral health related quality of life (MLQ) of your patients serves to confirm the indication and determine the therapeutic outcome. To this purpose, the individual questions, which are weighted only by the patient, are added to give an overall value ("never" = 0, "hardly" = 1, "occasionally" = 2, "often" = 3 and "very often" = 4.). Theoretically this will result in a value between 0 (= no restrictions to quality of life) and 56 (= maximum impairment of MLQ)

The questionnaire should be filled in by the patient alone, possibly in the waiting room, - before and approx. 2 weeks after treatment in each case.

This questionnaire only serves to assist you in your diagnosis, it does not suggest the need for treatment based on a certain score. A change in tooth shade is generally indicated with a score of >10 and a tooth shade of B4-C4 or darker or a difference of more than 8 shades of brightness to the adjacent teeth. The questionnaire can be ordered separately and free of charge from DeltaMed.

Contraindications:

Easywhite® Ready should not be used:

- in case of discoloration which can be removed through suitable polishing agents and rotating brushes or prophylaxis wedges as part of professional oral hygiene.
- during pregnancy and lactation as no studies are available
- for known allergies to any of the ingredients
- in case of exposed dentine
- in case of defective margins
- in case of untreated primary or secondary caries
- for heavy smokers and alcoholics
- persons under 18 years
- do not bleach under anesthetic

Adverse effects:

- Sensitivity and irritation of the teeth with more or less pronounced pain during or after treatment can occur in individual cases. As a rule these disappear within a short time. In case of excess sensitivity of the teeth during treatment, the exposure time of the bleaching agent must be shortened or treatment discontinued. Nonetheless, to obtain an acceptable bleaching result, fractionated whitening should be conducted over several sessions in such cases.
- Some studies refer to a temporary change in the organic dental matrix as well as a reduction in the microhardness of enamel and dentine, however without any pathological relevance.
- In the case of endodontic bleaching, an inadequately performed root canal filling which does not reach or exceed the enamel cement border, may lead to damage of the periodontium (external root resorption) or even loss of the tooth.
- It is essential for gingival protection to be extended over the tooth neck (approx. 1 mm). Inadequately applied gingival protection can lead to irritation of the gingiva through contact with peroxide. In this case the bleaching therapy must be discontinued and the tooth prepared anew after thorough rinsing and drying.
- Contains small amounts of organic amines. These can cause allergic reactions when in contact with skin or mucosa.

Interactions:

- Hydrogen peroxide impairs the radical polymerization of plastics. For this reason, composite fillings or bracket bonding should be carried out at earliest 2 weeks after bleaching treatment due to lacking adhesion to teeth.

Application:

Bleaching treatment should be conducted prior to new tooth-colored restorations as these cannot be whitened. Existing restorations could therefore possibly no longer match in terms of color shade.

- Pretreatment:

1. Clean teeth with appropriate polishing agent and rotating brush or prophylaxis wedge.
2. Determine initial tooth shade with suitable color scale (i.e. Vita), if necessary, document with photo.
3. Insert cheek/lip holder or similar.
4. Retract lips with dental rolls.
5. Apply gingiva protection (e.g. Easydam or coffer dam)
6. Protect patient's lips by applying petroleum jelly
7. Protect the patient's eyes with suitable protective glasses.

- Bleaching:

1. Place mixing tip on syringe, dispense and discard small amount of material. (Uneven filling of the individual chambers may lead to inhomogeneity in the beginning.)
2. Apply the material directly through the mixing tip at 1-2 mm thickness to the labial surfaces of the teeth to be bleached.

3. Stir the material on the teeth slightly from time to time (approx. every 10 - 15 minutes) with a spatula - alternatively, aspirate and replace with fresh material.
4. Overall duration of bleaching depends on the desired level of whitening and the type and extent of discoloration. Interval treatment of approx. 2x15 to max. 3x20 minutes per session is recommended to evaluate the interim results. Continuous treatment up to one hour maximum is also possible.
5. At the end of treatment, the remaining gel should be aspirated completely and carefully with a water jet, rinsed, and the bleaching result determined.
6. This should be followed by remineralization with a fluoride solution or gel. This can also considerably reduce discomfort in case of sensitivities.

Endodontic treatment of devitalized teeth:

- Following endodontic treatment, wait at least one week before commencing with whitening of a devitalized tooth.
- Remove root canal filling to max. level of enamel-cement border - better 1 mm above.
- Seal the root canal filling to apical with an approx. 1-2 mm thick glass ionomer cement layer to afford adequate protection of the root against peroxide.
- The preparation and duration of the bleaching process is the same as for vital teeth, in addition, the bleaching gel is also inserted into the root canal.
- After completing bleaching treatment, aspirate and rinse away the bleaching gel completely and seal the root canal temporarily (do not use composite).
- Wait approx. 2 weeks before finally sealing the root canal see also *Interactions*

Special notes:

- The bleaching effect can intensify for a few days after completing treatment.
- The result of bleaching treatment cannot be guaranteed as tooth discoloration may be due to a variety of causes.
- Any existing composite fillings are not bleached. The earliest these can be renewed, is two weeks after completing bleaching treatment.
- Orthodontic work (bonding brackets) should either be performed prior to bleaching therapy or no earlier than 2 weeks after (impaired adhesion to teeth)
- Please also observe the instructions for use for Easydam. Inappropriate application of gingival protection can lead to severe irritation and sensitization.

Warnings:

Component "A" contains highly acidic, 40% hydrogen peroxide (32% in ready-for-use neutral mixture) and component "B" contains highly alkaline components. Both are highly caustic individually. If stored improperly, the syringes may become pressurized and lead to uncontrolled spillage of gel when opening.

Causes serious eye damage. Harmful to aquatic life with long lasting effects. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In case of inadvertent skin contact, rinse the areas concerned with copious amounts water and moisturize with cream. In case of eye contact, immediately rinse with copious amounts of water and consult a doctor.

Notes on storage / shelf life:

Store at 4-12°C
Protect Easywhite® Ready against heat and sunlight.
Do not freeze Easywhite® Ready.
Do not use after expiry date.

Notes on disposal

Must be sent for special disposal in accordance with regulations on special waste.

Keep out of reach of children! Only for described use in oral cavities!

Delivery units:

Easywhite® Ready Intro Kit
1 x 2.5g Easywhite® Ready
1 x 1.5g Easydam
2 Automix tips

Easywhite® Ready Starter Set
2 x 5.0g Easywhite® Ready
2 x 3.0g Easydam
4 tips
4 Automix tips

Easywhite® Ready
5.0g and 2.5g single syringes
per 2 Automix tips

Easywhite® Ready complies with Standard EN ISO 28399

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This product was developed for use in dentistry and must be used in accordance with the instructions for use. The manufacturer cannot be made liable for any alternative use. In addition, the user is obliged to check the material at his own responsibility for its suitability and application for the intended purposes, especially if these are not listed in the instructions for use.

Key:

	Batch description		Recommended storage temperature
	Shelf life		Manufacturer
	Observe instructions for use		Corrosivity
	Protect against sunlight		Harmful if swallowed or if inhaled

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