

Easywhite® Ready

Instructions for use

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Description:

Easywhite® Ready is a 2-component material for whitening discolored teeth. Mixing the two components activates the bleaching agent. It is used exclusively by the dentist or by dental professionals under dental supervision in the dental practice. Patients over 18 years of age are treated with the exception of pregnant women, nursing mothers, very heavy smokers and / or alcoholics. The products are designed for treatment on a single patient only. The duration of treatment is determined individually and depends on the sensitivity of the teeth, the desired degree of whitening and the type and extent of tooth discoloration.

Composition (of the mixture):

Active ingredient: 32% hydrogen peroxide.

Purpose, indication and indications:

Easywhite® Ready is used for fast, medically indicated whitening of heavily discolored, vital and devitalized teeth whose color cannot be restored to *natural* or *normal* tooth color by professional tooth cleaning. Medically indicated tooth whitening is defined as discoloration that leads to a deterioration of the patient's (health-related) quality of life due to its abnormally deviating tooth color. If necessary, professional teeth whitening can also be used as an alternative to veneering the affected teeth with veneers or crowns.

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

- Tetracycline / minocycline discoloration
- Moderate to severe dental fluorosis
- Devital teeth (pulp necrosis) - e.g. due to trauma
- Genetic or age-related (degenerative) discolorations
- Porphyria or icterus
- Strong food deposits with penetration into the tooth substance (intrinsic discoloration due to extrinsic colorants)

Tooth shades are considered *natural* or *normal* as they usually occur in the population in terms of brightness, translucency and color. The Vita A1-D4 classical shade guide (for the most common shades found in nature), for example, is used as an aid for establishing the diagnosis and indication. Easywhite® Ready is used to whiten one or more teeth or parts of a tooth. It is also suitable for bleaching individual endodontically treated devitalized teeth including intracoronary bleaching.

A gingiva barrier (Easydam), cheek/lip restraints and cotton rolls are necessary to protect the gums, uninvolved dental areas and lips against the high-percentage hydrogen peroxide.

Contraindications:

Easywhite® Ready must not be used:

- in the case of discolorations that can be removed by suitable polishing agents and rotating brushes or prophylaxes during a professional dental cleaning.
- during pregnancy and the breastfeeding period due to lack of studies
- for inflamed gums
- in case of known allergy to organic amines
- for exposed dentin
- for defective filling margins
- For exposed necks of teeth
- in the case of untreated primary or secondary caries
- with very heavy smokers and / or alcoholics
- for persons under 18 years of age
- for anesthetized patients
- in the case of severely traumatized, devitalized teeth:
 - Tooth whitening, especially endodontic treatment of severely traumatized teeth, should generally be avoided because of the risk of unrecognized apical fissure formation and associated higher risk of cervical root resorption

Side effects:

- In individual cases, sensitivity and irritation of the teeth with more or less severe pain may occur during or after treatment. These usually disappear within a short time. In case of excessive sensitivity of the teeth during the treatment, the exposure time of the bleaching agent must be shortened or the treatment must be interrupted. In order to still achieve an acceptable whitening result, whitening should be performed in several sessions in such cases.

- Some studies indicate a temporary change in the organic tooth matrix and a reduction in the microhardness of enamel and dentin, without pathological relevance.
- In endodontic bleaching, inadequate root canal filling that does not reach or exceed the enamel-cement interface can result in damage to the periodontium (external root resorption) and even loss of the tooth.
- It is imperative that the gum protection is pulled over the neck of the tooth (approx. 1mm). Inadequately applied gum protection can lead to irritation of the gums due to contact with peroxide. In this case, the bleaching therapy must be discontinued and the tooth must be prepared again after careful rinsing and drying.
- Contains small amounts of organic amines. These may cause allergic reactions on contact with skin or mucous membranes.

Interactions:

- Hydrogen peroxide impedes the radical polymerization of acrylics. Therefore, composite fillings or bracket bonding should be carried out no earlier than 2 weeks after a bleaching treatment due to insufficient tooth adhesion.

Application:

Tooth whitening should be performed before restoring new tooth-colored restorations, as these cannot be whitened. Existing restorations may no longer match in color.

The patient should be positioned in a slightly seated position (45° angle) during tooth whitening.

- Pretreatment:

1. Taking a medical history and making a diagnosis by the dentist.
2. Perform a professional dental cleaning (PZR) ideally 1-2 weeks before the whitening treatment.
3. Determine the initial tooth shade with a suitable shade guide (e.g. Vita), document photographically if necessary.
4. General protective measures:
 - Cover the patient's lips for protection with suitable Coat lip care
 - Insert cheek/lip retractor.
 - Keep the lips off with cotton rolls.
 - Apply gingival protection (Easydam)
 - Protect the patient's eyes with suitable safety goggles

- Teeth whitening treatment:

1. Place mixing tip on syringe and squeeze out some material and discard. (The beginning may be inhomogeneous).
 2. Apply the material through the mixing tip directly to the labial surfaces of the teeth to be whitened in a thickness of approx. 1 - 2 mm.
 3. Leave the gel on for about 15-20 minutes.
 4. Remove the gel from the teeth by suction - do not rinse - and then apply a fresh layer of gel to the teeth. This procedure can be repeated three times.
 5. The maximum treatment time is up to 60 minutes. It depends on the desired degree of whitening, the type and extent of discoloration, and the severity of the irritations that occur. An interval treatment of approx. 2x15 to max. 3x20 minutes per session is recommended in order to be able to evaluate the intermediate result. Be sure to reduce the exposure time and cycles if the patient is sensitive.
 6. At the end of the treatment, first vacuum the remaining material and then carefully rinse completely with water spray.
 7. The whitening result can now be determined and documented.
- After teeth whitening:
After tooth whitening, remineralization with fluoride solution or gel is recommended. The same can also greatly reduce the insensitivity if sensitivities occur. Care should be taken to ensure that these agents are colorless.

Internal bleaching of endodontically treated non-vital teeth

The pretreatment and the whitening treatment are performed as described above; in addition, the material is placed in the root canal. It is not recommended to perform internal bleaching with light assistance.

- Wait at least one week after endodontic treatment before starting whitening of the devitalized tooth and make sure that the tooth is endodontically healthy. In particular, pay attention to crack formations.
- Review radiographs to ensure adequate apical endodontic seal is in place and to verify where the alveolar bone margin runs.
- Remove the filling material from the access hole to the depth you have defined based on the X-ray. Continue to remove the filling material and / or temporary endodontic materials to allow the whitening agent to come into contact with the inner structure of the tooth for best results.
- Seal the root canal filling apically with a layer of glass ionomer cement approx. 1-2mm thick to ensure adequate protection of the root against the peroxide. Remove the root canal filling to no more than the level of the enamel-cement interface - preferably 1mm above this.

- Apply Easywhite Ready into the cavity and ensure that the tooth structure is covered with 1-2 mm of gel. In addition, apply the gel to the outer surface of the tooth as well.
- After completion of the whitening procedure, remove the gel completely by suction and rinsing and seal the root canal temporarily (eugenol-free temporary restoration; do not use composite).
- It is imperative that the gum protection is pulled over the neck of the tooth (approx. 1mm). Inadequately applied gum protection can lead to irritation of the gums due to contact with peroxide. In this case, the bleaching therapy must be discontinued and the tooth must be prepared again after careful rinsing and drying.
- Wait approx. 2 weeks for final closure of the canal, see also under *Interactions*

Special Notes:

- The whitening result may increase for a few days after the treatment is completed.
- The result of teeth whitening cannot be guaranteed, because tooth discoloration can have different causes.
- Any composite fillings that may be present will not be whitened as well. These can be renewed two weeks after completion of the treatment at the earliest.
- Orthodontic work (bonding of brackets) should be performed either before tooth whitening or at the earliest 2 weeks after (impaired adhesion to the tooth).
- Incorrect application of the gum shield can lead to severe irritation and sensitization.
- The attached mixing tip can be used for all cycles of tooth whitening in one session. Opened components are intended for one treatment on one patient and are not reusable.

Warning:.

Easywhite Ready contains 3-diethylamino-1-propylamine. May cause allergic reactions.

The colorless component ("A") contains strongly acidic, 40% hydrogen peroxide (32% in the finished, neutral mixture) and the colored component ("B") contains strongly alkaline components. Both separately have a strong corrosive effect. If improperly stored, the syringes may be pressurized and uncontrolled gel may escape when opened.

Danger



Harmful if swallowed or inhalation. Causes serious eye damage. Wear protective gloves / protective clothing / eye protection / . IF IN EYES: Rinse cautiously with plenty of water for several minutes. Remove existing contact lenses if possible. Continue to rinse . IF INFECTED: Rinse out mouth. DO NOT induce vomiting. IF ON SKIN: Wash gently with plenty of soap and water.



Please always observe the current safety data sheet.

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

Reporting of serious incidents

Serious incidents are to be reported to DeltaMed GmbH, as well as to the competent authority.

Storage Instructions / Shelf Life:

- Storage at 4°-12°C
- Protect from heat and sunlight
- not freeze

If stored improperly, the syringes may be under pressure and uncontrolled gel may escape when opened. Do not use after the expiration date.

Notes on disposal

Easywhite Ready must be disposed of as hazardous waste in accordance with the regulations for the treatment of hazardous waste.

Caution. Never squeeze out *Easywhite Ready* double-chamber syringes with larger residual quantities into the waste container for disposal. Other combustible waste components (e.g. paper, etc.) may ignite due to the heat generated and cause a fire.

Delivery units:

Easywhite® Ready Intro Kit

1 x 2.5g Easywhite® Ready
2 mixing cannulas
1 x 1.5g Easydam
2 cannulas

Easywhite® Ready Starter Kit

2 x 5.0g Easywhite® Ready
4 mixing cannulas
2 x 3.0g Easydam
4 cannulas

Easywhite® Ready

5.0g and 2.5g single syringe
2 mixing tips each

Easywhite® Ready complies with DIN EN ISO 28399 standard. The product has been developed for use in the dental field and must be used in accordance with the instructions for use. The manufacturer accepts no liability for damage resulting from use in any other way.

Legend:



Batch code



Manufacturer



Catalogue number



Use-by date



Medical device



Protect from sunlight



Unique identifier of a medical device



Reuse on a single patient



Consult instructions for use



Exclamation mark



Temperature limit



Caustic effect



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