

home Illuminé™

Tooth Whitening Gels for Home Treatment

Illuminé™ home tooth whitening gels may be used alone or following treatment with an in-office tooth whitener.

Illuminé home tooth whitening gels contain the active ingredient of carbamide peroxide, which has shown to be most effective for the treatment of tooth discolourations at home.

Illuminé home 10% tooth whitening gel contains 10% carbamide peroxide, releasing H₂O₂ in a concentration of about 3.6%.

Illuminé home 15% tooth whitening gel contains 15% carbamide peroxide, releasing H₂O₂ in a concentration of about 5.4%, and in addition sodium fluoride.

COMPOSITION

Illuminé home 10%:

10% carbamide peroxide
Glycerine
Carboxypolymethylene
Sodium hydroxide
Water
Mint flavour

Illuminé home 15%:

15% carbamide peroxide
Glycerine
Carboxypolymethylene
Sodium hydroxide
Water
Mint flavour
Sodium fluoride

Both Illuminé home tooth whitening gels have pH values of approximately 6.0.

INDICATIONS

- Tooth discolouration caused by:
 - Staining from food, drinks and tobacco with penetration into the tooth substance
 - Age-dependent degenerative changes
 - Tetracycline (first and second grades) or minocycline medicamentation
 - Fluorosis, especially brown pigmentation
 - Pulp necrosis and/or endodontic treatment.
- Masking of enamel modelling.
- Genetically determined dark teeth.
- Whitening of discoloured teeth prior to restorative and/or prosthodontic measures, e. g. veneering.

The best results are with patients whose teeth are discoloured to yellow, orange or light brown.

CONTRAINDICATIONS

- Use during pregnancy or lactation.

2. Known allergy to hydrogen peroxide or other ingredients of the products.
3. Extrinsic stains which can easily be removed by professional tooth cleaning and which can be prevented by thorough oral hygiene.
4. Use in heavy smokers unless they refrain from smoking while wearing the tray.

WARNINGS

1. Illuminé home contains carbamide peroxide which may be irritating. Avoid contact with oral tissues, eyes and skin. If accidental contact occurs, flush affected area with generous amounts of water. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Care should be taken to assure that the reason for the discolouration is understood, in order to avoid masking of pathological conditions.
3. Keep out of reach of children.

PRECAUTIONS

1. Patients should always be warned of the potential sensitivity of the teeth and gingival tissues during the treatment.
2. Treat any uncared for caries and repair edge gaps in existing restorations, enamel gaps or cracks and free-lying regions of dentine, prior to whitening, to reduce the probability of the material reaching the pulp, resulting in hypersensitivity or inflammatory reaction.
3. Avoid exposure of known hypersensitive teeth and teeth with expanded pulp cavities to the whitening agent.
4. Assure trays are properly fitted to reduce the probability of swallowing the material, reduce the quantity of material required and avoid gingival contact.
5. Particular care should be given during insertion of the tray to carefully remove excess material as well as misapplied material from mucosal tissues and to avoid contact to skin and eyes.
6. If a patient experiences discomfort or sensitivity of the teeth or gingiva during treatment with Illuminé home, the following is recommended:
Patient should contact dentist for advice on appropriate steps to be taken.
For teeth sensitivity, try using slightly less Illuminé home gel or shorten the length of time for each exposure. Apply a topical fluoride gel by following the directions of the manufacturer.
For gingival sensitivity, be sure the gel tray is not rubbing against the marginal gingiva. Additional trimming of tray may be necessary.

INTERACTIONS WITH DENTAL MATERIALS

Existing tooth coloured restorations may not match the lighter shade of teeth after the treatment and may need to be replaced.

Illuminé home should be used before the placement of composites, veneers or crowns, in order to maintain a close match of tooth colour. We also recommend that the patient wait a minimum of two weeks after the treatment for the tooth discolouration to stabilise before performing anterior restorations.

Some old restorations (e.g. amalgams) may leave dark stains in the tray. This is normal and harmless.

ADVERSE REACTIONS

Patients may experience sensitivity from the use of carbamide peroxide-based products (exposed root surfaces, restorations with microleakage, exposed dentine, interproximal labial lingual areas).

Irritation of the oral mucosa may occur. Sore throat or nausea may be experienced if excessive gel is swallowed. Remove excess gel after the insertion of the tray with finger or toothbrush.

If sensitivity of the teeth or irritation of the oral mucosa continue although all precautions have been met, the patient should discontinue use and consult the dentist. Termination of treatment should be considered.

STEP-BY-STEP INSTRUCTIONS FOR DENTAL OFFICE

Initial Consultation

1. Review the patient's medical and dental history.
2. Perform an intraoral examination of the soft tissue, periodontal and teeth health.
3. Inform the patient on the expected treatment period which in standard cases is one to two weeks. However, depending on the nature of the stain, an extended treatment time of from six weeks to six months may be required to attain the desired effect.
4. A full prophylaxis (using Nupro® Prophy Paste) and fluoride treatment is recommended before starting the bleaching process.
5. The complete procedure should be discussed with the patient, reviewing any potential problems and side effects.
6. Provide the patient with the Illuminé home Patient Information.
7. Inform the patient that any existing tooth coloured restorations may not match the lighter shade of teeth after the treatment and may need to be replaced.
8. Use a suitable shade guide, e. g. Biodent¹ or Vita² Lumin Vacuum shade guide, to make a shade determination at baseline. Enter the teeth to be treated, the present and the desired shades into the patient's record.

Take Impression

Make an alginate or elastomer impression of the arch to be treated. (It is highly recommended that the teeth be treated one arch at a time, so that the patient can see the changes.)

INSTRUCTIONS FOR TRAY FABRICATION AND COMMUNICATION WITH DENTAL TECHNICIAN

The starter kit of Illuminé home includes an Instructions for Tray Fabrication booklet. Complete the Instruction Card on the last page of this booklet to make clear to the dental technician which teeth are to be treated. Provide Instructions for Tray Fabrication with completed Instruction Card to your dental technician along with your order.

STEP-BY-STEP INSTRUCTIONS FOR THE PATIENT

The Patient Information includes the following instructions. Please advise your patient accordingly:

Whitening Application Guide

1. Brush and floss teeth prior to wearing the tray.
2. Prior to first use of an Illuminé home syringe, replace cap by one of the applicators provided.
3. Open applicator by breaking off tip (retain tip to close applicator after use of syringe).
4. Following your dentist's instructions, place small amounts of gel towards the facial side of each tooth to be treated. DO NOT overfill the tray.
Close applicator on syringe and retain syringe for next treatment until empty. Each syringe contains approx. 3 to 5 applications.
5. Insert the gel tray in the mouth over the teeth. Wipe the excess material from the gum or tissue with your finger or toothbrush.
6. Wear the tray with gel throughout the night or as directed by your dentist (a minimum of 2 hours suggested).

¹ DENTSPLY DeTrey, Dreieich (D).

² Vita is a registered trademark of Vita Zahnfabrik H. Rauter GmbH & Co.

7. Do not eat or drink anything or smoke while wearing the tray.
8. After treatment, remove tray and rinse your teeth. Brush away any remaining gel.
9. Clean the gel tray with warm water and a toothbrush. Dry thoroughly and store in the tray holder.

STORAGE

Prior to use by the patient, refrigerate (2 - 8 °C) Illuminé home tooth whitening gels to maintain shelf life and assure the maximum effectiveness of the product.
Keep the Illuminé home kit away from heat or direct sunlight at all times.

BATCH NUMBER AND EXPIRY DATE

The batch number should be quoted in all correspondence which requires identification of the product.

Do not use after expiry date.

If you have any questions, please contact:

Manufacturer:

DENTSPLY DeTrey GmbH
De-Trey-Str. 1
78467 Konstanz
GERMANY
Phone +49 (0) 75 31 5 83-0

Distributor:

DENTSPLY Limited
Hamm Moor Lane
Addlestone, Weybridge
Surrey KT15 2SE
Phone (0 19 32) 85 34 22

© DENTSPLY DeTrey 2001-02-14