Opalescence®
Tooth Whitening Systems

Description:
Opalescence® is intended to be a dentist-supervised, take-home bleaching system, dispensed in unit dose syringes. It is a clear, flavored, high-viscosity, sticky, 10, 15, 20, 35%, or 45% carbamide peroxide gel (pH -6.5).
Opalescence® PF™ carbamide peroxide and/or hydrogen peroxide gels contain potassium nitrate, fluoride. They also have significant weight to reduce shade release from tooth dehydration. Opalescence take home products feature sustained release action and adhesive properties. All Opalescence products are gluten-free and kosher.

Indications:
Opalescence has been shown to effectively lighten the internal colors of teeth. In cases of tetracycline, adult monoclinic stains and brown fluorosis discoloration, Opalescence has obtained success of varying degrees. This is also true for discolorations caused by congenital, systemic, metabolic, pharmacological, traumatic or iatrogenic factors, erythroblastosis fetalis, jaundice and porphyria. Peroxide is a strong oxidizing agent. Bleaching occurs when the peroxide penetrates the enamel and dentin, oxidizing the offending stains within the tooth. Whitening occurs first and more rapidly with the enamel. For example, most tetracycline stains occur within the dentin and require more time to oxidize (whiten). Because restorative materials will not whiten, we recommend whitening dark teeth before restorative placement, and matching restorations to the new lighter shades (wait two weeks following bleaching procedures before placing restorations).

General Information:
Pay attention to tray design. The sticky, viscous, sustained-release gel behaves differently than other bleaching products and proper tray fabrication will help in avoiding or reducing irritation, limit peroxide contact to tooth surfaces and avoid contact with soft tissues. Following instructions yields results in days rather than weeks. The gel will stay active 8-10 hours in the mouth. Advise your patients on the following recommended wear times: Opalescence 10% for 8-10 hours or overnight; Opalescence 15% for 4-6 hours; Opalescence 20% for 2-4 hours; Opalescence 35% for 30-60 minutes; and Opalescence Quick 45% for 15-30 minutes. Observing wear times and properly using Opalescence can speed results and reduce long-term exposure to peroxide. A soft, thin tray material is best for fabrication of custom trays (Soft-Tray® 0.035") because it is more comfortable and the thin material occupies less of the patient's interocclusal space thereby minimizing awareness of the tray.

Pre-Treatment Procedure:
1. A diagnosis to ensure dental health must precede a bleaching treatment. Address failed restorations and/or areas of caries with temporary restorations. Exposed root surfaces may experience sensitivity, and if large areas are exposed, or if restorations are inadequate, patients may develop mild to moderately severe pain. Sometimes this can be addressed by simply trimming the tray back or covering exposed root surfaces with a bonding agent.
2. Remove calculus and extrinsic stains. If tissue is traumatized, wait one to two weeks before beginning bleaching treatment to minimize possible gingival sensitivity.
3. Wait two weeks following the bleaching procedure before matching and placing resin-bonded restorations, because color stabilization requires time and because residual peroxide ions will interfere with bond strengths. This is important before placing definitive tooth-colored restorations.
4. Occasionally, a slight purple discoloration may appear in the tray following bleaching adjacent to amalgam fillings.

Procedures:
1. Fabricate the tray using laboratory instructions or send a working cast/model with a prescription order form to Ultradent.
2. Use the provided patient instructions to instruct patient on the bleaching procedure, application of Opalescence, cleaning technique and tray care.

Ultradent Products, Inc.
Attn. Tray Fabrication
605 West Ultradent Drive (10200 South) South Jordan, Utah 84095

3. Demonstrate how to load tray by expressing one continuous bead of gel approximately half way up (or slightly lower) from the incisal edge on the facial side of the tray from molar to molar. This should use no more than 1/3 to 1/2 of a syringe. Instruct patient to clean tray with a soft toothbrush and tepid tap water after each use.
4. Occasionally tooth sensitivity and/or gingival irritation may require treatment. The treatment of choice is UltraeEZ®, a sticky, viscous gel that contains potassium nitrate and is worn in the Opalescence bleaching tray for up to one hour. Alternative treatments include the following:
   a. Patient may wear tray with a near-neutral, sticky viscous, fluoride gel (Flor-Opa®). Daytime use insulates teeth from cold, allowing sensitivity to subside.
   b. Appropriate administration of mild anti-inflammatory analgesics. Consult a doctor and/or pharmacist for drug interactions.
5. Evaluate patients every 3-5 days of treatment depending on patients' needs and degrees of progress. The number of days required for complete treatment depends on the type and severity of. For example, tetracycline stains require more treatment time than other types of stains.

Precautions:
1. Read and understand all instructions. Use recommended tray design and administer appropriate treatment regime to maintain optimal patient comfort.
2. Ensure gingival and general oral health prior to initiating treatment.
3. As a safety precaution, Opalescence should NOT be used during pregnancy. Consult a healthcare practitioner if you are breastfeeding or pregnant.
4. If patient has a known allergy or chemical sensitivity to peroxides, Carbopol, glycerin, etc., Opalescence is NOT to be used.
5. Mint and melon flavors can be irritating to some patients. If patient has a known sensitivity to mint or melon, use alternate flavors.
6. Restorations should be adequately sealed and all exposed sensitive dentin should be covered. If a history of sensitivity exists, treat with appropriate restoration, dentin bonding agent, or temporarily with dentin sealant.
7. Hypocalcified areas, which may not be visible to the naked eye, will whiten faster, thereby becoming more obvious during bleaching. Continue bleaching treatment until the unaffected tooth surface blends. Re-evaluate two weeks after bleaching treatment when tooth color has stabilized.
8. Monitor patient’s progress every few days, depending on severity of tooth discoloration. If only a mirror change is desired, treatments can be used more frequently with bleaching. Observe teeth with large metallic fillings closely to detect and prevent show-through.
9. If gingival or tooth discomfort persists (such as excessive temperature sensitivity), inform patient to discontinue treatment and make an appointment for evaluation.

Laboratory Instructions:
1. Pour impression with fast set plaster or dental stone. Pour alginate shortly after making impression to ensure accuracy. Trimming is less work if quantity of stone is kept to a minimum. However, have enough mass to ensure removal of model from impression without fracture. Trim base of cast parallel to the occlusal table on model trimmer to within a few millimeters of gingival margin for ease of manipulation. Palate and tongue areas are not poured or should be removed after plaster has set. Allow model to dry two hours.
2. Ultradent® LC Block-Out provides reservoir spaces in tray. Apply 0.5mm thickness of material onto desired labial surfaces and approximately 1.5mm shy of the gingival margin. DO NOT extend onto incisal edges and occlusal surfaces. This prevents tray margins from flexing open upon biting and/or impinging on soft tissues. Cure LC Block-Out by slowly scanning the resin for approximately 2 minutes (VALO®, VALO GRAND®). A hand-held intraoral curing light can be used (5 seconds per tooth). Wipe off oxygen inhibition layer.
3. Place tray material in a vacuum former (UltraVac™ or use Econo Vacuum Former), and heat until it sets approximately 1 inch. Activate vacuum and adapt softened plastic onto model. Cool and remove model from the vacuum former. To avoid distortion, cool the tray material completely before removing from the model.
4. Cut excess bulk of material away with serrated plastic trimmer (UltraComfort® Utility Cutters).
5. With small tactile scissors (Ultra-Trim™ Scalloping Scissors), carefully and precisely trim the tray to clear the gingival papillae, scallop into the gingival.
6. Use small flat cutter (Opalescence®, a

Return tray to model; check tray extensions. Gently flame polish edges, one quadrant at a time, with a butane torch. While still warm, immediately hold perpendicular to each segment firmly against model for three seconds with water-moistened gloved finger. If an area is short of the desired length, gently heat and push the tray material to the desired location. If this over-thins the tray material, fabricate a new tray.
7. Once tray is fabricated, clean with a soft brush and anti-microbial mouthwash rinse. Store tray in appliance case when not in use.
Keep reservoir below incisal and occlusal surfaces.
Reservoirs on facial aspect only.
Puddle block-out resin for reservoir approximately 0.5mm deep.
Keep reservoir approximately 1.5mm from gingiva.
Scallop around interdental papilla, trimming tray to clear line which is at the gingival height, flaring edges to reduce to desired height.

If one or more teeth are much darker than others (e.g. overly dark cuspid(s)), build reservoir(s) on that/those teeth only to balance end whitening results.
Teeth of lower esthetic concern need not receive reservoir.

Stay shy of gingiva, scalloping around interdental papilla.
Lapping onto gingiva may irritate tissues.

Sustained Release Test: After dental examination, Opalescence-filled customized tray (plastic membrane) was inserted. Small quantities of gel were removed at various intervals throughout the night for analysis of percentage of active ingredient.¹


DOCTOR INSTRUCTIONS

Opalescence Tooth Whitening Systems

For professional use only.
All Opalescence products are Gluten Free
For immediate reorder and/or complete descriptions of Ultradent’s product line, refer to Ultradent’s catalog or call Toll Free 1-800-552-5512. Outside U.S. call (801) 572-4200 or visit www.ultradent.com.

For product SDS please see our website:
www.ultradent.com