

Opalescence™ Tooth Whitening Systems

Description:

The Opalescence tooth whitening system is intended to be dentist-supplied and supervised. The whitening agents are clear, flavored, high-viscosity, sticky, peroxide containing gels. The agents are available in 10%, 15%, and 20% carbamide peroxide, and in 35% and 45% carbamide peroxide equivalent gels.

Opalescence™ PF gels contain potassium nitrate and sodium fluoride. They also contain significant water content to help prevent tooth dehydration and shade relapse. Opalescence whitening take home products feature sustained release action and adhesive properties. All Opalescence whitening products are gluten-free and kosher.

Indications:

Opalescence whitening has been shown to effectively lighten the internal colors of teeth. In cases of tetracycline, adult monocycline stains and brown fluorosis discoloration, Opalescence whitening 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).

General Information:

Pay attention to tray design. The sticky, viscous, sustained-release gel behaves differently than other bleaching products, so proper tray fabrication will help in avoiding or reducing irritation by limiting peroxide contact to tooth surfaces while avoiding contact with soft tissues. Following instructions yields results in days rather than weeks. The gel will stay active 8-10 hours in the mouth. Observing wear times and properly using Opalescence gels can speed results and reduce long-term exposure to peroxide. A soft, thin tray material is best for fabrication of custom trays (Sof-Tray™ Classic Sheets 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 comprehensive exam to ensure dental health must precede a bleaching treatment. Address any temporary restorations and caries, both initial and/or under failed restorations, as well as identify any sensitive root exposure areas. 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 7-10 days 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 teeth with amalgam fillings. This discoloration is normal.
5. Teeth with large amalgam restorations may appear darker than other bleached teeth because the internal restoration becomes more visible through the bleached enamel. The patient should be made aware that this may require an esthetic restoration following bleaching.
6. On rare occasion, teeth do not respond to bleaching and occasionally the original tooth colors return shortly after completion of treatment.
7. When not in use, trays should be stored in the appliance cases provided in each Opalescence whitening kit.
8. If patient is unable to follow the treatment safely, this whitening treatment should not be recommended.

Procedure:

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 whitening, cleaning technique and tray care. Explain treatment regimens to patient:
 - a. Wear Opalescence 10% gel 8-10 hours or overnight, Opalescence 15% gel 4-6 hours, Opalescence 20% gel 2-4 hours, Opalescence 35% gel for 30-60 minutes, and Opalescence Quick 45% gel for 15-30 minutes.
 - b. Some dentists prefer nighttime bleaching regimens for their patients because they offer maximum results with less bleaching material use, due to decreased salivary flow during sleep. The lowered mouth activity

- prevents "pumping" of material from tray. Note: Only Opalescence 10% gel should be worn overnight.
- c. Alternatively, treatments can be from 15 minutes to several hours per day, depending on the patient's needs, level of sensitivity and day-to-day activities.
- d. Stopping for multiple days does not jeopardize continued bleaching when re-initiated.
3. Demonstrate how to load the 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 1/3 to 1/2 of a syringe. Instruct patient to clean tray with a soft toothbrush and water after each use.
4. For patients with known tooth sensitivity, pre-op and post-op treatment with UltraEZ™ desensitizing gel, Opalescence sensitivity relief toothpaste, and/or Enamelast™ fluoride varnish is recommended. Depending on the severity of sensitivity, other treatment options are available.
5. Follow up with patient treatment. The number of days required for complete treatment depends on the type and severity of tooth stains. For example, tetracycline stains require more treatment time than other types of stains.

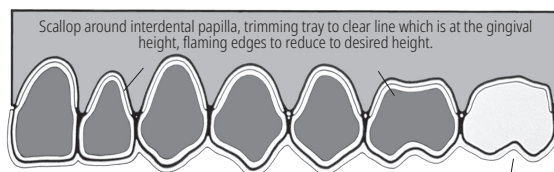
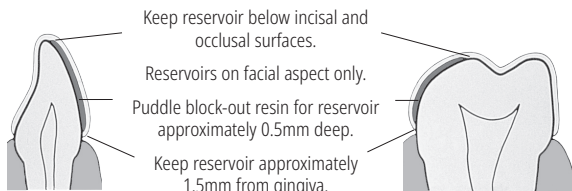
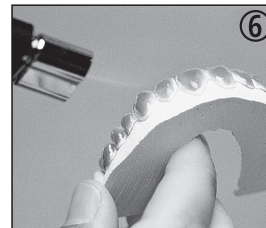
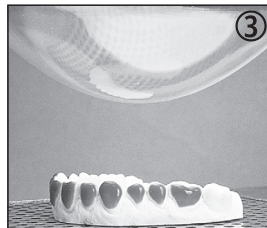
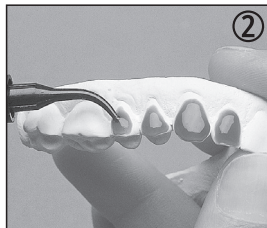
Precautions:

1. Read and understand all instructions. Use recommended tray design and administer appropriate treatment regime to maintain optimal patient comfort.
2. Verify gingival and general oral health prior to initiating treatment.
3. Understand each patient's expectations before beginning treatment. Inform patients that existing crowns, tooth colored fillings, etc., do not whiten. Also, for a small percentage of the population, their teeth will not appreciably whiten.
4. If more than mild gingival or tooth discomfort is experienced (such as excessive temperature sensitivity), inform patient to discontinue treatment and make an appointment for evaluation.
5. Pregnant or breastfeeding women, or patients with serious health concerns should not whiten. Consult their primary care provider prior to treatment.
6. If patient has a known allergy or chemical sensitivity to any of the ingredients in Opalescence whitening do not use. Mint or melon flavor can be irritating to some patients. If a patient has a known sensitivity to flavorings, the non-flavored variant should be selected.
7. Instruct patients to avoid swallowing large amounts of gel or water used to rinse gel residue from the teeth.
8. Avoid treatment if patient may swallow or aspirate tray.
9. Avoid contact with eyes
10. Because restorative materials will not whiten, we recommend whitening dark teeth before restorative placement.
11. Wait 7-10 days following bleaching procedures before placing restorations.
12. 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.
13. Hypocalcified areas (white spot lesions), 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.
14. Monitor patients' bleaching progress to prevent bleaching beyond the desired level of whitening or degree of translucency.
15. Maintain control of Opalescence whitening agent, dispensing only what is needed to accommodate use until next evaluation appointment.
16. Opalescence whitening agent is supplied in preloaded 1.2ml syringes. Material is NOT to be injected, and patients should be instructed to dispose of syringes when empty.

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. Palate and tongue areas are not poured or should be removed after plaster has set. Allow model to dry two hours.
2. For reservoir spaces, apply Ultradent™ LC Block-Out resin approximately 0.5 mm thick onto the labial surfaces. Stay about 1.2 mm from gingival line. Do not extend onto incisal edges or occlusal surfaces. Using VALO™ LED curing light, cure each tooth 5 seconds.
3. With vacuum former, heat tray material (Sof-Tray classic sheets) until it sags approximately 1 inch. Adapt plastic over model. To avoid distortion, cool the tray material completely before removing from the model. Note: Patients with heavy occlusion or bruxers may require a thicker 0.060" tray.
4. Cut excess bulk of material away with serrated plastic trimmers (Ultradent™ Utility Cutters).
5. With small tactile scissors (Ultra-Trim™ Scalpoling Scissors), carefully and precisely trim the tray to the clear line which is at the gingival height. Scalpol edges to avoid contact with gingival tissue.
6. Return tray to model; check tray extensions. Gently flame polish edges, one quadrant at a time, if necessary, with a butane torch. While still warm, immediately hold periphery of each segment firmly against model for three seconds with water-moistened gloved finger. If this over-thins the tray material, fabricate a new tray.

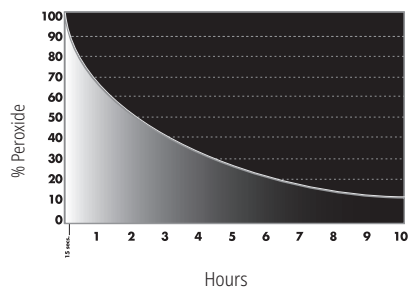
Ultradent Products, Inc.
Attn: Tray Fabrication
505 West Ultradent Drive (10200 South)
South Jordan, Utah 84095



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.

Sustained Release Test: After dental examination, Opalescence gel-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



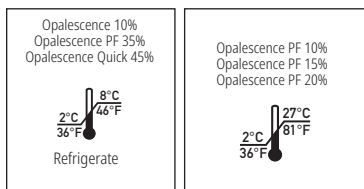
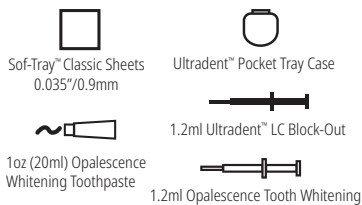
¹ MATIS, BRUCE A., et al. "In vivo degradation of bleaching gel used in whitening teeth." The Journal of the American Dental Association 130.2 (1999): 227-235.



Stay shy of gingiva, scalloping around interdental papilla.



Lapping onto gingiva may irritate tissues.



DOCTOR INSTRUCTIONS



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

Opalescence[®]
tooth whitening systems



Manufactured by
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