

52-21 Opalescence Sustained Release Whitening Gel (Project 96-67) (06/97)

Opalescence Sustained Release Whitening Gel is a clear, syringe-based, 10 percent carbamide peroxide home-bleaching product. The treatment process with Opalescence is similar to that of other home-bleaching products. The clinician makes an alginate impression, and the laboratory pours a cast and fabricates a thin tray. The bleaching agent is then provided to the patient with application instructions. Ultradent claims that the bleaching gel's sticky, adhesive nature increases its effectiveness and makes it possible to achieve results in days that normally take weeks when using other bleaching products. The gel is available in regular and mint flavors. The Doctor Kit of Opalescence contains twelve syringes of the whitening gel, two sheets of tray material, one syringe of LC Block-Out resin, two shade guide cards, a tube of Tooth Whitening Creme, and a tray case. The LC Block-Out resin is applied to the cast to produce a reservoir area in the tray for the gel. The product is also available in Refill and Patient Kit versions. The Refill Kit contains forty syringes of Opalescence and two shade guide cards while the Patient Kit contains eight syringes of the gel, one tube of Tooth Whitening Creme, and a tray case. Each of the three packaging versions can be ordered as Regular (regular flavor) or Mint (mint flavor). This project evaluated the Doctor Kit.

Manufacturer:

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095
(800) 793-5216
(801) 572-0600 FAX

Suggested Retail Price:

\$39.95 Doctor Kit (REF/UP 303 - regular flavor; REF/UP 306 - mint flavor), each kit contains:
12 (1.2 cc) syringes of whitening gel with dispensing tips
2 Sof-Tray tray sheets (0.035-inch thick)
one (1.2 cc) syringe of LC Block-Out resin
2 shade guide cards
1 (1 oz) tube of Opalescence Tooth Whitening Creme
1 pocket tray case

Government Price:

\$33.79 Doctor Kit (item numbers and contents as listed above)

ADVANTAGES:

- + Produced excellent results; all ten clinical evaluators reported their patients were "Satisfied" or "Very Satisfied" after treatment.
- + Syringes make gel placement easy because of their thin nozzle tip.
- + Tray fabrication, doctor, and patient treatment instructions are complete and well illustrated.
- + pH (6.56) matches the value claimed by Ultradent; near-neutral pH should prevent possible enamel demineralization during treatment.
- + Thickness and tackiness of gel should help retain it in tray.
- + Tray thickness is appropriate.
- + Patients found paper shade guide useful in charting the progress of their treatment.
- + Expiration date and lot number are printed on box.
- + Bears the American Dental Association Seal of Acceptance.

DISADVANTAGES:

- Approximately half of the patients felt the whitening toothpaste was of limited benefit.
- Some patients (approximately 10%) objected to the gel's mint flavor, judging it to be too "spicy" or "hot."
- More expensive than several other currently-available home-bleaching products.

SUMMARY AND CONCLUSIONS:

Opalescence was well received by clinicians and patients during this evaluation. The bleaching gel is somewhat thick and tacky, which help it stay in the tray during use. The tray material provided with Opalescence is thick enough to prevent it from being worn away but thin enough to keep it from causing occlusal problems. The gel is available in two flavors (regular and mint) and Ultradent plans to introduce a third flavor (melon). The flavor evaluated in this project (mint) was acceptable to most of the patients, however some found it to be spicy and hot. Side effects were reported by 13 percent of the treated patients. The few reported, such as gingival irritation and tooth sensitivity, were minor. The product is more expensive than several other currently-available home-bleaching products, however DIS has not evaluated the other products to determine their effectiveness and side effects. All of the clinical evaluators reported their patients were "Very Satisfied" or "Satisfied" with the results produced by Opalescence. **Opalescence Sustained Release Whitening Gel** is rated **Acceptable** for use by the federal dental services.