

Product Description

Opalescence™ Pro hydrogen peroxide whitening gel is for in-office use only. The 2-barrel mixing syringe ensures maximum strength for each application and precise dosing of the activator. One barrel contains a unique chemical activator, which is combined with a second barrel containing hydrogen peroxide.

Delivery Form(s)

- 1.2 ml Delivery Syringe
- Recommended delivery tip
 - Black Mini™ Tip

Indications for Use/Intended Purpose

Opalescence Pro whitening is for in-office use only. It is applied by the dental professional for whitening one or more teeth. Opalescence Pro in-office whitening is also used on non-vital teeth, including in-office intracoronal whitening. Opalescence Pro in-office whitening is an alternative, conservative method (compared to crowns, veneers, etc.) for whitening dark, internally discolored teeth caused by predisposing factors such as disease, traumatic or iatrogenic injury, congenital, systemic, metabolic, or pharmacological influences. These can include but are not limited to elevated bilirubin levels, tetracycline and adult minocycline stains, porphyria, erythroblastosis fetalis and high fluoride intake during tooth development.

Contraindications

- Pregnant or nursing women should not use teeth whitening products
- or patients or users with allergy concerns, refer to product allergen document available at ultradent.com. If allergic reaction is observed, rinse exposed area thoroughly with water and have the patient consult their physician.

Warnings and Precautions

- Use only recommended tips
- Avoid direct contact of the active surface of the tooth whitening product with the gums and/or salivary flow
- For patients with known tooth sensitivity, pre-op and post-op treatment with UltraEZ™ desensitizing gel, Opalescence™ Whitening Toothpaste with Sensitivity Relief, and/or Enamelast™ fluoride varnish is recommended

- Some patients may experience temporary discomfort of the gums, lips, throat, tongue, or teeth. Should any of these symptoms persist or worsen after discontinuing use, or in cases of severe discomfort, call your dental professional.
- If the product is ingested, drink large amounts of water and contact a physician. If the product is aspirated, seek immediate medical attention.
- Inform patients restorative materials will not whiten, and so we recommend whitening dark teeth before restorative placement
- Wait at least 7–10 days after whitening procedures before placing adhesive restorations
- Patients with serious health concerns should consult their primary care provider prior to treatment
- Avoid contact with eyes. Rinse immediately if product comes into contact with them.
- To prevent additional irritation, gingival and general oral health should be evaluated prior to initiating treatment
- Etching enamel or prophy paste polishing before any whitening procedure is not recommended and does not potentiate the whitening process but can cause sensitivity
- Restorations should be adequately sealed, and all exposed sensitive dentin should be covered. If a history of sensitivity exists, treat with appropriate restoration or blocking agent such as dentin bonding or temporarily with dentin sealant agent or fluoride varnish.
- Monitor patient's whitening progress to prevent whitening beyond the desired level of whitening or degree of translucency
- Rinse empty syringes and used tips thoroughly with water before disposal to avoid fire
- Bring syringes to room temperature before mixing
- Patient and dental professionals must wear protective eyewear with side shields when handling this product
- If gel is not red after mixing, do not use. It was not mixed properly.
- If soft tissue sensitivity or irritation occurs, instruct patient to use and OTC oral topical anesthetic gel or vitamin E oil
- Contains sodium fluoride

Stepwise Instructions

Preparation

1. Do an oral exam and treat areas of concern, including but not limited to exposed dentin, decay, etc. prior to treatment.
2. Determine and record baseline shade. Use photographs when indicated for baseline documentation.

Use – Mixing Opalescence Pro In-Office Whitening

1. Ensure syringes are securely attached.
2. Depress the small clear plunger into the middle small clear syringe to rupture internal membrane and combine whitener and activator.
3. Press the plunger of the red syringe, pushing all contents into the clear syringe.
4. Press the contents of the clear plunger completely back into the red syringe.
5. To thoroughly mix activator with whitening gel, push stems back and forth continually and mix 25 times each side.
6. Press all mixed gel into the red syringe.
7. Twist to separate the two syringes and securely attach the recommended tip (Black Mini tip) onto the red syringe.
8. Verify flow, consistency, and that the color is red before applying intraorally. If resistance is met, replace tip and re-check. If gel is not red, do not use and refer to Step 2 in the "Use – Mixing Opalescence Pro In-Office Whitening" section.

NOTE:

- Opalescence Pro in-office whitening should be used within 10 days of mixing. Keep refrigerated between uses.
- Refer to mixing card included.

Isolation - OpalDam™ Resin Barrier (Recommended Isolation)

1. Remove Luer lock cap from OpalDam™ resin barrier and securely attach recommended delivery tip. Refer to Warnings and Precautions.
2. Verify flow prior to applying intraorally.
3. Rinse and dry teeth and gums thoroughly. Place Ultradent IsoBlock™ bite block and self-supporting lip/cheek retractors (or Ultradent Umbrella™ retractor) to avoid Opalescence Pro whitening gel from contacting any soft tissue.
4. Apply OpalDam resin barrier along the gingival margin, overlapping approximately 2–3 mm onto the enamel. Begin and finish one tooth beyond the most distal tooth that is being whitened. Use barrier to isolate tooth/teeth to be treated.
5. Express resin through any open embrasures onto the lingual tissue to completely seal and cover exposed papilla.
6. Use the mouth mirror to ensure there are no gaps exposing the underlying gingiva. If so, apply resin to the gap.
7. Light cure 20 seconds per arch using a scanning motion. When isolating a single tooth, scan for 5 seconds. Carefully check resin cure with an instrument.

Isolation – Rubber Dam (Alternative Isolation)

1. Place rubber dam to isolate the teeth being whitened.

Use – Applying Opalescence Pro In-Office Whitening

1. Apply a 0.5–1.0 mm thick layer of gel to the labial surface of the tooth.
2. Allow gel to remain on the teeth 20 minutes per application, periodically checking on patient comfort and suctioning of saliva.

NOTE: Avoid contact with soft tissue or salivary flow. If chemical irritation occurs due to the intraoral soft tissue coming into contact with the peroxide gel, immediately wipe the gel from the tissue using a wet gauze and rinse the area well. Tissue should return to normal within 20–30 minutes. Refer to Warnings and Precautions.

3. Suction gel from teeth using the Luer Vac and SST™ (Surgical Suction Tip) or a surgical suction tip. To avoid gel splatter, do not use water while suctioning gel. When no gel is visible, lightly rinse and air dry. Use caution not to dislodge the isolation barrier or rubber dam seal.
4. Evaluate shade change after each application and monitor patient for sensitivity and irritation. If persistent sensitivity occurs, discontinue use.
5. Repeat steps under section "Applying Opalescence Pro In-Office Whitening" for no more than 3 applications if desired results have not been achieved. Do not exceed 3 applications per visit.
6. Retreat as necessary using professional judgement.

Cleanup

1. Suction gel from teeth using the Luer Vac and SST (Surgical Suction Tip) or a surgical suction tip. To avoid gel splatter, do not use water while suctioning gel. When no gel is visible, thoroughly rinse and suction.

2. If using OpalDam resin barrier, gently slide the tip beneath the resin barrier to remove or remove rubber dam.

Notes

- For patients with known tooth sensitivity, treatments pre- and post-tooth whitening with UltraEZ desensitizing gel, Opalescence Whitening Toothpaste with Sensitivity Relief, and/or Enamelast fluoride varnish is recommended. Depending on the severity of sensitivity, other treatment options are available.

Endodontically Treated Teeth

1. Establish the expectations of the patient. Explain any esthetic limits before proceeding. Before photos are recommended.
2. Verify healthy periodontal tissues and quality endodontic treatment.
3. Remove all restorative and root sealing material from the coronal pulp chamber, 2–3 mm below healthy gingiva. Place a 2 mm thick conventional glass ionomer, resin modified glass ionomer, or bonded flowable composite resin to seal the endodontically treated canal. Verify set of material before proceeding.
4. Follow "Isolation" instructions above isolating both the labial and lingual sides of the tooth.
5. Express gel into access opening and onto the labial and the lingual surface. Do not seal the access opening. Do not use as a walking bleach.
6. Allow gel to remain for 20 minutes per application.
7. Suction gel from the tooth surface and access opening using the Luer Vac and SST (Surgical Suction Tip) or a surgical suction tip. To avoid gel splatter, do not use water while suctioning gel.
8. When no gel is visible, lightly rinse and air dry. Use caution not to dislodge the isolation barrier or rubber dam seal.
9. Evaluate shade change and repeat, if necessary.
10. Follow "Cleanup" instructions to remove gingival barriers.
11. Seal access with a preferred barrier in access preparation using a cotton pellet and allowing a minimum 2–3 mm thickness for temporary restorative material such as J-Temp™ temporary resin or UltraTemp™ Regular luting material.
12. Wait 7–10 days following whitening procedure before placing the permanent restoration as whitening materials interfere with bonding agents.

Notes

- If additional whitening is desired, re-schedule and repeat the Opalescence Pro in-office whitening procedure above or use Opalescence™ Endo whitening.
- Regression is to be expected. Follow-up whitening treatment every 3–5 years is recommended.
- If you have any questions regarding this product, please find additional information at ultradent.com/products/categories/whitening/in-office/opalescence-pro.

Processing

To avoid cross-contamination, wipe syringe with an intermediate level disinfectant between uses and use a disposable barrier sleeve. If a barrier sleeve is not used, syringe should be treated as single-use.

Storage and Disposal

Store according to outer package label.

Dispose of waste according to local rules, guidelines, and regulations.

- Dispose of waste according to local rules, guidelines, and regulations.
- Before disposing of syringes aspirate water into the syringe and express liquid down the drain. Repeat a couple of times before disposing of the syringe. Make sure any gauzes used are rinsed with water.

Miscellaneous Information

- Hypocalcified areas (white spot lesions), which may not be visible to the naked eye, will whiten faster, thereby becoming more obvious during whitening. Continue whitening treatment until the unaffected tooth surface blends. Re-evaluate two weeks after whitening treatment when tooth color has stabilized.
- For a small percentage of the population, their teeth will not appreciably whiten
- Some amalgam fillings may leave a dark purple color in your whitening tray; this is normal
- Teeth can re-stain over time, so do touch up teeth whitening treatments as necessary

Report any serious incident to the manufacturer and the competent authority. ultradent.com / 1.800.552.5512 / 801.572.4200



Patient and clinician must wear safety glasses when product is mixed and applied



Keep out of reach of children

For professional use only

Opalescence™ Pro
In-Office Professional Whitening System

Manufactured by:
Ultradent Products, Inc.
505 West Ultradent Drive (10200 South)
South Jordan, Utah 84095 USA
Manufactured in the USA from globally sourced materials



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