

Opalescence™ Boost 40% 牙齿美白系统

ZH

产品名称：
牙齿美白胶

规格型号
PF 40%

产品组成

该产品由美白胶和催化剂组成，其中美白胶为1.043ml/支，催化剂为0.157ml/支，美白胶的主要成分为过氧化氢、水和二氧化硅，催化剂的主要成分为丙三醇、硝酸钾、氢氧化钾和氟化钠。

产品介绍：

Opalescence Boost 40%是含40%过氧化氢成份的医用强效漂白凝胶。混合喷射注射器确保每次使用时药品的鲜度，也确保了催化器的准确剂量。一支针管中含有氟化钠和硝酸钾等独特的化学催化剂，临床表明均有减少龋齿、脱敏的作用。另一只针管含浓缩过氧化氢。混合后，Opalescence Boost形成一种1.1%氟化物和3%硝酸钾的混合液。OpalDam Green是一种具有被动粘性（密封性）和反光性的独特的光固化树脂，其甲基丙烯酸酯基强度足以构成屏障，但同时可以从缝隙和切口处轻松去除。

适用范围：

该产品仅用于牙科诊所美白牙齿，适用于16岁以上身体健康人群，因烟草、可乐、茶、咖啡、酱油等有颜色物质造成的外源性染色牙的牙齿美白。

禁忌症

对产品组成中任一成分过敏者禁用。

注意事项：

Opalescence Boost 40%强效漂白凝胶仅限院内使用，必须由医生操作完成对单颗或多颗牙齿及牙齿特定部位的漂白，也可以/或用于在诊所内进行的快速漂白。由于修复材料无法漂白，因此推荐在修复前先行漂白治疗（在漂白两个星期后再进行粘合性修复），经验表明多数经过治疗的牙齿在治疗后12-24小时内会继续变白，将问题牙齿漂白至较为自然的色泽有利于选择较浅的修复材料。Opalescence Boost既可单独使用，亦可与牙医监督的 Opalescence美容漂白系统搭配使用。OpalDam Green在诊所漂白和微研磨等过程中可以保护牙齿周围的软组织。

预备操作：

1. 在漂白约定时间的两周前清洗牙齿。
2. 确定并记录底色。可通过对比照片来记录色泽的变化。
3. 在混合药剂前让Opalescence Boost达到室温。
4. **警告：在混合并使用本产品时，患者、临床医生和助手都必须佩戴保护性眼镜和手套。**

使用说明：

隔离-用OpalDam Green (建议的隔离步骤)

1. 放置张口器 - UltradentIsoblock。
2. 拧下OpalDam Green的螺口帽，在注射器上拧紧带刻度的“一次性Black Mini”tip针头。
3. 注入口腔内以前，检查液体的流动情况。
4. 使用带支撑的嘴唇/面颊牵开器。
5. 彻底冲洗并烘干牙齿，清洗时特别留意第三牙槽。
6. 不停地将OpalDam Green挤到牙龈上，与牙釉质重合约0.5毫米。在一颗牙齿上挤出一条树脂带，然后拓展到位于漂白牙齿后面的那颗牙齿。
7. 继续挤，直到做成4-6毫米、宽1.5-2毫米的厚条。
8. 在有缝隙的地方把树脂透过缝隙挤到牙齿和临近的牙龈上，彻底将缝隙堵住，对牙间乳头和牙齿牙龈组织形成保护。
9. 用口腔镜，检查牙体长轴，在任何微小的缝隙处再抹树脂。
10. 以扫描的方式对每个牙床用固化光照射20秒进行固化。

隔离-橡皮障

1. 位于漂白牙齿后面的牙齿两侧夹上放置橡皮障的夹钳。
2. 连接橡皮障和框架之前，沿橡皮障下露出的牙龈挤出一条橡皮障密封剂或固化的树脂带。
3. 连接橡皮障和框架。沿牙齿边缘将橡皮障翻下。检查最佳密封效果。

混合Opalescence Boost：

1. 混合前，检查注射器是否牢固。按说明上的图示做。
2. 把红色针筒中的化学药剂挤进透明针筒。
3. 用力将注射器透明推杆快速推入中间的小透明针筒。这样做会使推杆内膜破裂，混合催化剂和漂白成分。
4. 继续推透明针筒已让所有的溶液进入红色的针筒。
5. 反向重复上述动作，快速混合至少25次以上（每个方向12-13次）。
6. 把所有的混合溶液推入红色针筒。
7. 扭开这两个针筒，在红色针筒上安装Black Mini™ tip针头。

注意：混合后的Opalescence Boost须冷藏保存，于10天后失效。

使用Opalescence Boost：

1. 在纱布或混合垫上观察液体的流动状况，确保在口腔中使用前能流动顺畅。如果感觉有阻力，切勿进行下一步操作。更换新的针头，在实际使用前再次测试。仅使用推荐针头。

- 注意：如果仍然感到有阻力，勿用该针管，跟Ultradent客服联系，更换针管。
2. 涂沫0.5到1.0毫米厚（图5）的Opalescence Boost。先把凝胶涂抹在牙齿的唇面，然后再轻轻拓展到切面/咬合面。
 3. 让凝胶在牙齿上停留20分钟，不时查看凝胶的情况，在凝胶变薄或需要重抹的地方重新涂沫。
 4. 用螺旋真空（LuerVac）和SurgiTip针头或外科用针头吸除牙齿上的凝胶。为避免凝胶飞溅，吸除时切勿用水。小心不要碰到树脂隔离障或橡皮障。
 5. 每次使用后评估色调变化，监测患者是否出现过敏和刺激反应。若持续出现牙齿敏感或软组织刺激，请停止使用。
 6. 将第2-5步重复两次，或直至达到理想效果。每次治疗使用不超过3次。
 7. 如需进一步美白且未见明显过敏现象，可安排患者在3-5天后重复治疗。

清洗：

1. 用螺旋真空（LuerVac）和SurgiTip针头或外科用针头吸除牙齿上的凝胶，然后再用气/水枪和大功率吸附装置冲洗牙齿。
2. 用牙科专用工具，将探针轻轻地伸进OpalDam Green的下面，取下屏障。检查并清理埋藏在牙缝里的任何残留物。
3. 如果用了橡皮障，按清洗第1步，取下夹钳、橡皮障和框架。
4. 用压舌板、软牙刷、牙线、强力吸清除橡皮障密封剂，并用气/水/水流彻底冲洗。

注意：

- 美白单颗、几颗或一颗牙的某个部分的步骤同上，但仅将美白剂抹在变色部位。
- 如果患者在治疗以后发生过敏，可在治疗后立即用UltraEZ类的硝酸钾产品。然后每天敷用15分钟到1小时，直到症状缓解为止。
- 进一步美容性美白治疗须等Boost治疗24-48小时后再行使用居家美白系统如Opalescence PF/Go 牙齿美白凝胶或Opalescence Tréswhite Supreme。
- 不建议在漂白前进行牙釉质酸蚀操作，该操作并不能加强漂白效果。

根治治疗过的牙：

1. 拍摄X光片，检查牙槽高度。
2. 彻底清除牙髓室的所有填充物。
3. 将1-2毫米厚的玻璃离子或树脂改良型玻璃离子放入髓室底或冠向放在牙槽槽。

1. 填充物的厚度应该能够完全密封“封闭”根管内部和物质。
4. 按上文中的“隔离”步骤操作，将牙的唇面和舌面隔离开来。
5. 按照上文中的“混合”步骤操作。
6. 注入口腔内以前，检查液体的流动情况。
7. 将凝胶挤进敞开的牙髓室及牙齿唇面。
8. 让凝胶在口腔内保留10分钟。
9. 用螺旋真空（LuerVac）和SurgiTip针头或外科用针头吸除牙齿上的凝胶。为避免凝胶飞溅，吸除时切勿用水。小心不要碰到树脂隔离障或橡皮障。
10. 凝胶清除后，漱口并风干牙齿，小心不要碰到树脂隔离障或橡皮障。
11. 查看色泽变化，重复第7-10步的操作。
12. 如果用了三次以后，还没有出现理想疗效，则需停止治疗。
13. 按照上说明中的“清洗”步骤，取下橡皮障。
14. 用非丁香暂时冠桥材料密封牙髓室。
15. 美白治疗完成两周后再作最后的粘接或放置美容修复材料。

注意：

- 如果需进一步美白，建议用Opalescence Endo家用美白剂。
- 美白过的牙齿会有回归原来色泽的情况。可将牙齿稍微过度漂白。图7：彻底漱口，让水对着大功率吸附装置。

警告/预防措施：

1. **混合和应用Boost时，临床医生和患者都必须佩戴带侧护套的保护性眼镜！**
2. 在使用前，仔细阅读并看懂“化学品安全说明书”以及所有说明。
3. 混合前，先让针筒温度达到室温。
4. 在放入口腔内以前，观察所有针筒内液体的流动状况。如果感觉有阻力，更换新的针头，再次测试。如果仍然感到有阻力，勿用该针管，跟Ultradent客服联系，更换针管。
5. 仅使用推荐针头。
6. 置于儿童触摸不到的地方。
7. 处理本产品时必须佩戴保护性手套。
8. 治疗前必须确保牙龈和口腔健康。
9. **丢弃针管时必须先用水桶稀释并清除所有残留漂白药剂，接着冲入下水道或厕所，然后用2-3夸脱/升的清水冲洗。切勿在装有可燃物（纸类产品、橡胶等）的垃圾箱中丢弃，因为这样有可能导致自燃。用水清洗用过的纱布。**
10. 已知对过氧化氢、二醇物、丙烯酸或其它树脂过敏的患者禁用Opalescence Boost。如果出现过敏反应，出现皮炎或红疹，去看外科医生。
11. 美白前完成所有的修复治疗。
12. 抹了OpalDam Green的地方反复出现泡沫，清洗掉凝胶，查看是否有泄露。轻轻擦干该处，重新抹上OpalDam Green。如果继续有问题，清除隔离障，重抹。
13. 遮盖所有暴露的牙本质敏感区域。
14. 有时候会存在临床上看不到的钙化不全现象。由于钙化程度不同，上述区域的漂白速度要快于普通釉质。在患者继续漂白的过程中，这些区域将开始接近其它部分牙齿的色泽。
15. 本产品不用于注射。
16. 不用时须冷藏。
17. 避热和/或避晒。
18. 混合的凝胶可保存10天，并可在10天以内再用。重新接好针筒，每次使用前用中效消毒剂擦针筒，起到消毒作用。
19. 妥善处理针头和针筒。

储存与运输

牙齿美白胶应在2°C-27°C储存。牙齿美白胶为塑料注射器包装，外包装为纸盒包装。允许使用一般交通运输工具，但须防止运输过程中的剧烈冲击、震动及雨雪淋湿。

生产日期
见外标签

产品有效期：

24个月
失效期见注射器外所示，见下图：



X026=批号 X026=月份 X026=年份

仅供专业人士
远离儿童

如需立即再定购和/或获取Ultradent完整产品线的说明，请参考Ultradent目录或拨打免费热线：1-800-552-5512
美国以外请拨打(801)572-4200，或访问www.ultradent.com

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标签所用图形、符号的解释

	合格标识		置于儿童不能触及之处
	健康危害		参阅说明
	生产企业		腐蚀性
	2°C~27°C 储存		混合并使用本产品时，患者和临床医师必须佩戴安全护镜

配件清单

无

注册人/生产企业

名称：Ultradent Products, Inc. 美国皓齿制品有限公司
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代理人/售后服务单位

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医疗器械注册证编号/产品技术要求编号：国械注进20193171560

说明书编制或者修订日期：

编制日期：2019年1月15日
修订日期：2019年7月10日

Opalescence™ Boost 40%
Tooth Whitening System

EN

Description:
Opalescence Boost 40% is a 40% hydrogen peroxide, medical power bleaching gel. The jet mix syringe ensures freshness for each application and precise dosing of the activator. One barrel contains a unique chemical activation with sodium fluoride and potassium nitrate, which have been demonstrated to reduce caries susceptibility, lower sensitivity, and improve enamel microhardness. The other barrel contains the concentrated hydrogen peroxide. When mixed, Opalescence Boost results in a 1.1% fluoride and 3% potassium nitrate concentration.

OpalDam Green is a unique, light-reflective, passively adhesive (sealing) light-cured resin. Its methacrylate base is designed with sufficient strength to maintain a barrier yet is easily removed from embrasures and undercuts.

Indications for Use:

Opalescence Boost 40% power bleaching is for medical in-office use only. It is applied by the dentist for bleaching one or more teeth, parts of a tooth, and/or for accelerated chairside whitening techniques. Opalescence Boost is also used on nonvital teeth, including in-office intracoronary bleaching.

Opalescence Boost is an alternative, conservative method for treating dark, internally discolored teeth (compared to crowns, veneers, etc.) caused by disease, injury, or medical treatment such as congenital, systemic, metabolic, pharmacological, traumatic, or iatrogenic factors such as dental fluorosis, jaundice, tetracycline, and adult minocycline stains, porphyria, trauma, and erythroblastosis fetalis.

Because restorative materials will not whiten, it is recommended that teeth are whitened prior to placing esthetic restorations (wait two weeks after bleaching procedures before placing adhesive restorations). Our experience shows that most treated teeth continue to whiten 12 to 24 hours after whitening treatment is completed. Bleaching problematic teeth to a more natural shade will optimize restorative shade matching. Use Opalescence Boost alone or in conjunction with the dentist-supervised Opalescence Cosmetic Bleaching System.

OpalDam Green is used to protect soft tissue adjacent to the teeth during in-office bleaching, microabrasion, etc.

Preliminary Procedures:

1. Clean and polish teeth approximately two weeks prior to bleaching appointment.
2. Determine and record baseline shade. Use photographs when indicated for baseline documentation.
3. Prior to mixing, bring Opalescence Boost to room temperature.
4. **WARNING:** Patient, clinician and assistant must wear protective eyewear and gloves when mixing and applying this product.

Directions for Use:

1. Isolation - OpalDam Green (recommended isolation): Place Ultradent Isoblock.
2. Remove Luer lock cap from OpalDam Green and securely attach a Black Mini tip.
3. Verify flow prior to applying Intraorally.
4. Place self-supporting lip/check retractors.
5. Rinse and dry teeth thoroughly, especially the gingival third.

Opalescence™ Boost 40%
Tooth Whitening System

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



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6. Express a continuous bead of OpalDam Green along the gingival margin, overlapping approximately 0.5 mm on to the enamel. Beam and finish the bead one tooth beyond the most distal tooth that is being bleached.
7. Continue building the barrier apically until it is 4-6mm high and 1.5-2.0mm thick.
8. Express resin through any open embrasures on to the lingual tissue completely sealing and covering exposed papilla.
9. Using the mouth mirror, look up the long axis of the teeth and re-apply resin to any minute openings.
10. Light cure 20 seconds per arch using a scanning motion. Carefully check resin cure with an instrument.

Isolation - Rubber Dam

1. Apply rubber dam placing ligated clamps bj-laterally and one tooth distally to the teeth to be whitened.
2. Before attaching rubber dam to the frame, apply a bead of rubber dam sealer or light-cured resin barrier at the gingival margin beneath the dam.
3. Attach dam to the frame and invert rubber dam at the gingival border. Check for optimum seal.

Mixing Opalescence Boost

1. Check that syringes are securely attached before mixing. Follow pictorial diagram included in this kit.
2. Depress the red plunger forcing the contents of the red syringe into the clear syringe.
3. Quickly and forcefully, depress the small clear plunger into the middle small clear syringe to rupture internal membrane and combine bleach and activator.
4. Continue depressing the clear plunger so all gel is in the red syringe.
5. Reverse the action and mix a minimum of 50 times (25 on each side).
6. Press all mixed gel into the RED syringe.
7. Twist to separate the two syringes and attach the Black Mini tip onto the red syringe.

NOTE: Mixed Opalescence Boost expires after ten (10) days if refrigerated.

Applying Opalescence Boost

1. On gauze or mixing pad, verify flow of all syringes prior to applying intraorally. If resistance is met, replace tip and re-check. Use only recommended tips.
- NOTE:** If resistance continues, DO NOT use that syringe and contact Ultradent Customer Service for replacement.
2. Apply a 0.5-1.0mm thick layer of gel to the labial surface of the tooth and slightly onto the incisal/occlusal surfaces.
3. Allow gel to remain on the teeth 20 minutes, periodically checking and re-applying areas that have thinned or need replenishing.
4. 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. Use caution not to dislodge the isolation barrier or rubber dam seal.
5. Evaluate shade change after each application and monitor patient for sensitivity and irritation. If continued tooth sensitivity or soft tissue irritation occurs, discontinue use.
6. Repeat steps 2-5 two times, or until desired results are achieved. Do not exceed 3 applications per visit.
7. If additional whitening is desired and no significant sensitivity is noted, re-schedule patient in 3-5 days for repeat treatment.

Clean-up

1. Suction gel from teeth using the Luer Vac and SST™ (Surgical Suction Tip) or a surgical suction tip then thoroughly rinse teeth with air/water spray and the high volume suction.
2. Using a dental instrument, gently slide the tip beneath the OpalDam Green and lift off. Check and remove any interproximal remnants.
3. If using a rubber dam, follow Clean-up Step 1, remove clamps, dam, and frame.
4. Remove rubber dam sealer with spatula, soft toothbrush, floss, suction and firm air/water spray.

NOTES:

- A single, few, or a partial tooth can be bleached using this same instruction and applying the bleach only to those specific areas of discoloration.
- For post-op sensitivity, use potassium nitrate products such as UltraEz immediately after treatment and for 15 minutes to 1 hour per day until sensitivity subsides.
- For additional cosmetic whitening, wait 24 - 48 hours after Boost treatment before beginning a take-home whitening system such as Opalescence GO.
- Etching enamel before any bleaching procedure is

not recommended and does not potentiate the bleaching process.

1. Check radiograph for alveolar crest height.
2. Completely remove all filling material from the pulp chamber.
3. Place a 1-2mm glass ionomer or resin modified glass ionomer filling on pulpal floor at or coronally to the alveolar crest height. Filling material should be thick enough to completely seal the obturation or rest and material.
4. Follow "Isolation" instructions above isolating both the labial and lingual sides of the tooth.
5. Follow the "Mixing" instructions above.
6. Verify flow prior to applying intraorally.
7. Express into access opening and the labial surface.
8. Allow gel to remain in the tooth 10 minutes.
9. Suction gel from access opening and tooth 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. Use caution not to dislodge the isolation barrier or rubber dam seal.
10. When no gel is visible, lightly rinse and air dry. Use caution not to dislodge the isolation barrier or rubber dam seal.
11. Evaluate shade change and repeat steps 7-11.
12. If desired results are not achieved after 3 applications, discontinue treatment.
13. Follow "Clean-up" instructions to remove gingival barriers.
14. Seal access with a non-eugenol provisional restorative.
15. Wait 2 weeks before final bonding or placing esthetic restoration.

NOTES:
• If additional whitening is desired, Opalescence Endo walking bleach is recommended.
• Regression of whitening should be expected. Compensate by slightly over bleaching the tooth.
Precautions and Warnings:

1. Clinician and patient must wear protective eyewear with side shields when mixing and applying Boost.
2. Carefully read and understand MSDS and all instructions before using.
3. Bring syringes to room temperature before mixing.
4. Verify flow of all syringes prior to applying intraorally. If resistance is met, replace tip and re-check. If resistance continues, DO NOT use that syringe and contact Ultradent Customer Service for replacement.
5. Use only recommended tips.
6. Keep out of reach of children.
7. Wear protective gloves when handling this product.
8. Gingival and oral health should be confirmed before using this product.
9. Before disposing of syringes, aspirate water into the syringe to dilute and remove all residual bleaching gel. Dispose of liquid into a drain or toilet followed by 2-3 quarts/liters of water. DO NOT dispose of syringes in waste containers containing burnable materials (paper products, rubber, etc.) as spontaneous combustion can result. Rinse used gauze with water.
10. Do not use on patients with a known sensitivity to peroxides, glycols, acrylates or other resins. If allergic reaction, dermatitis or rash develops, consult a physician.
11. Complete all restorative treatment prior to treatment.
12. If bubbles reoccur along the margin of the OpalDam Green, rinse off gel and check for leakage. Lightly dry area and re-apply OpalDam Green. If problem persists, remove dam and re-apply.
13. Cover any sensitive areas of exposed dentin. Areas of hypocalcification, though not clinically visible, may exist and will whiten quicker than surrounding enamel. As patient continues to whiten, the areas will begin to blend.
14. Material is not to be injected.
15. Refrigerate product when not in use.
16. Keep out of direct heat and/or sunlight.
17. Mixed gel can be saved and used within 10 days. Re-connect syringes, disinfect by wiping syringe with an immediate level disinfectant between uses.
18. Dispose of tips and syringe properly.

EN- For professional use only
ZH- 仅用于专业用途

EN-Destroy after use.
ZH- 用後銷毀



EN- See Instructions
ZH- 參閱說明



EN- Keep away from heat/sunlight
ZH- 避免熱源/日曬



EN- Do not re-use to avoid cross contamination
ZH- 切勿再使用，以免交叉感染。



EN- Patient and clinician must wear safety glasses when product is mixed and applied
ZH- 混合并使用本产品时，患者和临床医师必须佩戴安全护镜



EN- Catalog Number
ZH- 目录号



EN- Recycle
ZH- 回收



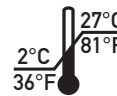
EN- Use by date
ZH- 有效期



EN- Keep out of reach of children
ZH- 置于儿童不能触及之处



EN- Lot Number
ZH- 批号



<p>Activator Gel 催化剂</p> <p>EN- Health hazard ZH- 健康危害</p> <p>EN- Corrosive ZH- 腐蚀性</p>	
<p>Bleaching Gel 美白胶</p> <p>EN- Health hazard ZH- 健康危害</p> <p>EN- Corrosive ZH- 腐蚀性</p>	
<p>Activator Mixed with Bleaching Gel 催化剂美白胶混合凝胶</p> <p>EN- Health hazard ZH- 健康危害</p>	