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Introduction

Background

Discoloration of the teeth can be the result of aging, tobacco use, chromogenic foods, medications and pulpal pathology. The most severe tooth discolorations result from systemically prescribed medications and excessive fluoride intake during tooth formation. To combat this, there are several tooth-whitening systems available including take-home systems, in-office systems, in-office light-activated systems and toothpaste which aims to remove only extrinsic tooth discolorations. With the exception of toothpaste, many of these systems make use of peroxides.

The first use of hydrogen peroxide to whiten the teeth occurred back in 1884. Since then, researchers have attempted to enhance hydrogen peroxide’s ability to rapidly whiten teeth. Methods have been developed to bleach non-vital teeth as well as vital teeth. Non-vital bleaching often involves relatively high concentrations of hydrogen peroxide (e.g., 35% hydrogen peroxide) being placed into artificially created cavities in the tooth aimed to bleach (or whiten) the tooth from the inside-out, while vital tooth bleaching typically involves lower concentrations of hydrogen peroxide (e.g., 3-10% hydrogen peroxide) being applied directly to the natural surface of the healthy tooth, usually in the form of a sticky gel, aimed at bleaching the tooth from the outside-in.

Zaris™ White & Brite Tooth Whitening Gel is a tooth whitening system marketed exclusively to dental professionals for in-office and take-home use, under the supervision of a dental professional. Zaris White & Brite gel utilizes carbamide peroxide as the active ingredient and is available in 10%, 16%, or 30% concentrations. Zaris White & Brite gel is intended for vital tooth bleaching only.

Product Description

Zaris White & Brite gel is applied by means of a custom-fitted tray. The Zaris White & Brite 30 gel system is intended to be used in the dental office, under the direct supervision of a dental professional, while Zaris White & Brite gel (10% and 16% strengths) are designed for take-home use.

Zaris White & Brite gel can be used to whiten individual teeth or several teeth in an arch.

In water, carbamide peroxide breaks down to hydrogen peroxide and urea, with approximately one-third of the mass of the carbamide peroxide being hydrogen peroxide and about two-thirds being urea [i.e., molecular weight of carbamide peroxide = 94.07g/mol, molecular weight of hydrogen peroxide = 34.01g/mol and molecular weight of urea = 60.07g/mol]. A gel containing 10% carbamide peroxide contains only about 3.5% hydrogen peroxide. It is widely accepted that hydrogen peroxide is the agent that provides the tooth whitening benefit, even though carbamide peroxide is often the ingredient that is added during manufacturing. This is analogous to 0.243% sodium fluoride being added to over-the-counter dentifrice resulting in a fluoride ion concentration (the active ingredient concentration) of 0.1099% or about 1,100 ppm.
Table 1 shows the carbamide peroxide concentrations and corresponding hydrogen peroxide concentrations contained in the three Zaris™ White & Brite Tooth Whitening Gel formulations. These levels of active ingredients are similar to or less than that of other bleaching products on the market. Some take-home products may contain as much as 14% hydrogen peroxide and products available exclusively through the dental office may contain much higher concentrations.

<table>
<thead>
<tr>
<th>Name</th>
<th>Carbamide Peroxide Concentration</th>
<th>Hydrogen Peroxide Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zaris White &amp; Brite gel 10%</td>
<td>10%</td>
<td>3.5%</td>
</tr>
<tr>
<td>Zaris White &amp; Brite gel 16%</td>
<td>16%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Zaris White &amp; Brite gel 30%</td>
<td>30%</td>
<td>10.5%</td>
</tr>
</tbody>
</table>

Zaris White & Brite gel is a transparent, tacky gel. It is supplied in syringes, each containing 3.5g of gel. The gel is dispensed into a custom-fitted tray that is designed to hold a thin layer of gel against the facial surface of the teeth during the treatment period (1 to 2 hours). Zaris White & Brite gel is available in a Deluxe Kit (with 6 syringes), Express Kit (with 4 syringes) and Touch-up Kit (with 2 syringes). Each syringe is labeled with a calibrated scale to ensure the proper dispensing of product (approximately 0.6g per application). The amount of gel contained in the syringe determines the number of applications per syringe (approximately 6).

**Typical Composition**

Tooth whitening gels typically contain few ingredients. Each of the ingredients has an important function and serves to ensure a high quality, stable formulation. Typical ingredients include:

**Glycerin**

Glycerin is used as the main carrier for the active ingredient (peroxide).

**Carbamide (Urea) Peroxide**

Carbamide (Urea) Peroxide is the active ingredient that provides the whitening benefit. When wetted with saliva, urea peroxide is rapidly converted to hydrogen peroxide.

**Polycarboxylic Acid**

Polycarboxylic acid is used as a thickening agent. The polycarboxylic acid gives the whitening gel its viscous attribute and therefore helps hold the whitening gel against the teeth during the treatment period and helps control the release of hydrogen peroxide through the treatment period.

**Peppermint Oil (Mentha Piperita)**

Peppermint oil is added to provide a pleasant taste during the treatment period.

**Evaluations**

**Tooth Whitening**

Zaris White & Brite tooth whitening system was evaluated in a double-blind clinical trial evaluating both efficacy and safety. Thirty-seven subjects were assigned to one of three treatment groups: Zaris White & Brite gel, Rembrandt® Lighten or a peroxide-free placebo gel. At baseline and after six weeks of treatment (24 total hours of exposure to gel), the mean tooth shade of the maxillary central incisors was evaluated by comparing tooth color to the Bioform Color Oriented shade guide. Average tooth shade changes observed for the thirty-two subjects who completed the study were 6.00, 3.73 and 0.78 for Zaris White & Brite gel, marketed tooth whitening gel and placebo gel respectively. Zaris White & Brite gel was shown to whiten teeth significantly more than the placebo gel and similar to the marketed tooth whitening gel (p < 0.05).

**Reservoirs (blocking)**

There has been some debate regarding the importance of reservoirs in the tooth whitening process. Reservoirs (also known as blocking) aim to hold additional peroxide gel in contact with the tooth surface to enhance the whitening benefit and is also thought to prevent overflowing of bleach onto the soft tissue. In a study involving twenty-one subjects ranging from 20 to 50 years of age, the relative whitening performance of several different gels delivered from a specialized tray was evaluated. Baseline tooth color was determined by two independent observers using a Vita Lumin shade guide. Each patient was then fitted with a maxillary tray containing reservoirs on the right side and no reservoirs on the left side of the dentition. One week after the treatment period ended, tooth color was again determined by two independent observers using a Vita Lumin shade guide. The right and left sides exhibited similar tooth color. One patient exhibited a frosted area on a reservoir facial surface, not seen on the side without a reservoir. This study demonstrates that reservoirs do not provide enhanced whitening benefits, compared to when no reservoirs are used.
Effects on Composite Resins

An in vitro experiment was conducted to evaluate the effects of carbamide peroxide bleaching gels on two popular composite resins. Composite resin samples were prepared using conventional procedures and then incubated in Zaris™ White & Brite Tooth Whitening Gel, a mixture of Zaris White & Brite gel and saline, saline or a catalytically decomposed version of Zaris White & Brite gel (d-White & Brite). Specimens remained in the solutions for 45 days and solutions were replaced daily. Following exposure to solutions, tensile strength and color of the composite restorations were determined quantitatively according to ADA Specification Number 27. The results indicated that Zaris White & Brite tooth whitening gel did not have an adverse significant affect on either of the composite resins.

![Graph showing Tensile Strength after 45 days of Treatment](image)

Effects on Enamel and Dentin

An in vitro experiment evaluating the effect of Zaris White & Brite gel on the elemental composition of human enamel and dentin was conducted. Extracted human incisors were partially submerged in Zaris White & Brite tooth whitening gel for a period of 45 days and solutions were replaced daily. Incisor portions not submerged remained in a humid environment to simulate soaking in saliva. Following the treatment, incisors were fractured to permit evaluation of treated and untreated portions and then subjected to chemical analysis by electron spectroscopy. The results demonstrated that exposure to Zaris White & Brite gel did not result in a detrimental alteration in the composition of either tissue.

![Graph showing Percent Composition in Enamel of Elements/Functional Group](image)

![Graph showing Percent Composition in Dentin of Elements/Functional Group](image)

Value, Clinical Effectiveness, Quality of Directions for Use and Lab Tests

An independent clinical research institute that evaluates dental materials, devices and concepts for efficacy and clinical usefulness, conducted performance tests on 23 popular at-home bleaching products, including the Zaris™ White & Brite Tooth Whitening System. Zaris White & Brite gel (referred to simply as White & Brite in the publication) was given the second-highest overall score. Parameters evaluated included cost to the dentist, tooth color change, peroxide kinetics during use, directions for use, viscosity, taste, user satisfaction, total contact time and pH. An overall score was calculated based on the all of the parameters, except for pH.
Technical Guide

Tray Fabrication

An alginate impression is taken registering all tooth surfaces and gingival margins.

Strong stone is used to create a model.

Excess stone is trimmed to allow proper adaptation of the tray material to tooth surfaces only. Once trimmed, only a few millimeters of the gingival should remain. The palate and tongue areas should be removed, leaving a U-shaped model for custom tray formation.

The tray material is heated so that it drops approximately 1 1/2 inches (40mm). The heated tray material is then lowered onto the model and vacuum is applied. When complete adaptation is achieved, the vacuum is switched off.

The newly formed tray is allowed to cool and is then removed from the model. The tray is then trimmed along the gum-line to ensure patient comfort and minimize gingival irritation during treatment.

Gel Application/Treatment

Teeth should be brushed and flossed before each application of Zaris™ White & Brite Tooth Whitening Gel.

Snap cap off of dispensing tip by twisting and bending slightly. Each syringe has 6 calibration lines. Each line represents one tray application.

Apply a small amount of Zaris White & Brite gel in the facial side of each tooth space.

Replace the cap back on the end of the dispensing tip and snap it in place. This protects the Zaris White & Brite gel from exposure and maintains shelf-life.

Place custom tray over your moistened teeth. Do not squeeze the tray. Allow any excess gel to escape naturally and remove excess gel using a toothbrush or tissue. Most whitening occurs during the first hour of each application. Wear custom tray once or twice each day for 1 to 2 hours per application or as recommended by your dentist. For Zaris White & Brite 30 gel, only the dentist can determine if a third daily application is appropriate.

Upon completion of each application, remove custom tray, rinse with water and brush clean with toothbrush. Additionally, rinse or brush teeth to remove any excess whitening gel.

Continue using Zaris White & Brite gel (10% or 16% strengths) uninterrupted each day until all treatments have been completed or the desired results are achieved.
Instructions for Use

Zaris™ White & Brite 30 Tooth Whitening Gel

Description
Zaris White & Brite 30 gel is used for the lightening of teeth. The gel is applied by means of a custom-fitted tray. The treatment is carried out by the dental professional in the dental office.

Indications
• Whitening of discolored vital teeth
• Whitening of discolored non-vital teeth

Individual teeth or several teeth in a row can be whitened.

The whitening treatment in the dental office can be combined with a follow-up at-home treatment by the patient. A lower concentration of Zaris White & Brite gel (10% or 16%) is used for applications at home.

Discoloration can be caused by:
• medications, such as tetracycline, minocycline
• fluorosis
• food-related stains
• age-dependent changes

Contraindications
Zaris White & Brite 30 gel should not be used by:
• pregnant or lactating women
• children
• patients who are heavy smokers
• patients who consume large quantities of alcoholic beverages
• patients who are known to be allergic to any of the material’s ingredients
• patients with teeth which are cervically exposed
• patients who have untreated primary or secondary caries
• patients who have restorations with marginal gaps

Side effects
In individual cases, temporary irritation of the mucous membrane or sensitivity of the teeth may occur. These side effects usually subside within a short time after the treatment is finished or discontinued.

Step-by-step instructions

Pretreatment
Prior to the application of Zaris White & Brite 30 gel, the patient’s medical and dental history should be carefully examined and professional tooth cleaning carried out.

Tray fabrication
A properly fabricated tray will improve the effectiveness of the whitening process. Snugly fitting trays will improve patient comfort and reduce the chance of irritating the mucous membrane. It is advisable to use Zaris™ White & Brite Tray Material only.

1. Take impression, fabricate a stone model and trim it for optimal lingual adaptation.
2. Heat tray material on a vacuum former until it sags 1 to 2 cm (0.4 to 0.8 inch), adapt to model and place under vacuum for 30 seconds.
3. After cooling, remove tray from stone model and remove excess material.
4. Carefully scallop the tray about 0.5 mm short of the gingival margins, using either fine scissors or a blade.
5. Place tray back on the stone model to assess accuracy of fit. Final shaping and defining of periphery may be accomplished with a coarse acrylic polisher.

Application
1. Check for an accurate fit of tray.
2. Remove the cap from the resealable application tip of the syringe by twisting it off. Place a small amount of gel toward the facial side of each tooth space in the whitening tray. Use the calibration markings on the syringe as a guide when extruding the material; a syringe usually contains enough gel to fill approx. three upper and lower trays. Note: Do not apply too much gel into the trays. Overfilling does not result in faster or better results, and may cause sensitivity.
3. Place the tray with gel over the patient’s teeth. Note: Do not squeeze the tray when inserting it.
4. Remove excess gel by means of a cotton roll or tissue – prevent the patient from swallowing the material!
5. Determine how long the patient should wear the tray. Twenty to thirty minutes are usually sufficient. Depending on the individual requirements of the patient, the whitening procedure may be repeated. Note: The patient must not eat, drink or smoke while wearing the tray.
6. Remove the tray after the whitening process has been completed.
7. Remove any remaining gel and rinse thoroughly.
8. Clean the tray with a toothbrush under running water.
9. Repeat steps 2 to 8 for further applications.

Tip
Tooth whitening with Zaris White & Brite 30 gel can be used as initial whitening treatment. The whitening procedure can be continued by the patient at home using a lower concentration of Zaris White & Brite gel.

Notes
The patients should be reminded of the following points in particular:
• Avoid, or at least try to minimize, the consumption of coffee, tea, red wine, colas and smoking to prevent the chance of discoloration occurring in the teeth.
• Avoid the consumption of citrus fruits and fruit juices on the day of the treatment, as they can promote sensitivity.
• Overfilling the tray with tooth whitening gel does not result in faster or better results, and may cause sensitivity.
• Zaris White & Brite 30 gel should be applied before the placement of new tooth-colored restorations, as the tooth whitening gel does not whiten any existing dental restorations.

The treatment with Zaris White & Brite 30 gel should be completed at least two weeks before the placement of a new restoration. Existing restorations may not match the lighter shade of the teeth after the treatment and may need to be replaced.
Warning
Contains carbamide peroxide and is an irritant. Avoid contact of the gel with the skin, mucosal tissues and eyes. If contact with the eyes occurs, wash the areas affected with copious amounts of water and seek medical advice.

Storage
• Store material at 2–8°C (36–46°F).
• Protect Zaris™ White & Brite 30 Tooth Whitening Gel from heat and sunlight.
• Do not freeze Zaris White & Brite 30 gel syringes.
• See date of expiration for shelf life; observe the information on temperature.
• Do not use after the date of expiration.

Keep out of the reach of children!
For dental use only!

Zaris™ White & Brite Tooth Whitening Gel (10% and 16% Strengths)

Indications
Individual teeth or several teeth in a row can be whitened. Discoloration can be caused by:
• medications, such as tetracycline, minocycline
• fluorosis
• food-related stains
• age-dependent changes

Contraindications
Do not use while pregnant or lactating.

Warnings
Keep out of reach of children. Do not swallow gel.

Precautions
• Wait at least one hour between treatments.
• Avoid citrus fruits and juices until your treatments have been completed, since they may cause sensitivity.
• Do not apply excess gel in your custom tray. This does not lead to quicker results and may cause sensitivity.
• Do not eat, drink or smoke while wearing your custom tray.
• Reduce or eliminate consumption of coffee, tea, red wine, cola and tobacco, since they may contribute to tooth staining during (and after) your whitening treatment.

Instructions for Use for Dentists
1. Take impression, fabricate a stone model and trim it for optimal lingual adaptation.
2. Heat tray material on a vacuum former until it sags 1 to 2cm (0.4 to 0.8 inch), adapt to model and place under vacuum for 30 seconds.
3. Carefully scallop the tray about 0.5mm – 1mm short of the gingival margins, using either fine scissors or a blade.
4. Place tray back on the stone model to assess accuracy of fit. Final shaping and defining of periphery may be accomplished with a coarse acrylic polisher.

Instructions for Use for at-home applications
1. Brush and floss your teeth before each application of Zaris White & Brite gel.
2. Snap cap off of dispensing tip by twisting and bending slightly. Each syringe has 6 calibration lines. Each line represents one tray application. Apply a small amount of Zaris White & Brite gel in the face-side of each tooth space.
3. Place the cap back on the end of the dispensing tip and snap it in place. This protects the Zaris White & Brite gel from exposure and maintains shelf-life.
4. Place your custom tray over your moistened teeth. Do not squeeze the tray. Allow any excess gel to escape naturally and remove from your gums using a toothbrush or tissue.
5. Most whitening occurs during the first hour of each application. Wear your custom tray once or twice each day for 1 - 2 hours per application or as recommended by your dentist.
• Your dentist can advise you if a third daily application is appropriate for your situation.
6. Upon completion of each application, remove your custom tray and rinse it with water. Rinse or brush your teeth to remove any excess whitening gel.
7. Continue using Zaris White & Brite gel uninterrupted each day until all of your treatments have been completed or the desired results are achieved.

Storage and Use
• When not wearing your custom tray, store it in your tray case.
• Replace the cap on the end of the dispensing tip after each use.
• Store syringes in a cool, dry place. Refrigerate if possible.
• Do not freeze Zaris White & Brite gel syringes.
• Do not expose Zaris White & Brite gel syringes to excessive heat or prolonged periods of sunlight.

If you have any questions or concerns regarding your treatments, consult your dentist.
Questions and Answers

Can Tooth-Colored Fillings Be Whitened?
No. Whitening treatments can not whiten tooth colored fillings, crowned (capped) or veneered teeth. This is one more reason to seek the advice of a professional before using any whitening product. As part of your treatment plan, your dentist will advise you on esthetic options to ensure a totally beautiful smile.

What Causes Teeth To Discolor?
Teeth discolor over time; how rapidly they discolor is partly due to genetics and personal habits. In addition to the natural aging process, teeth gradually discolor from drinking coffee, tea, soda and juices. Some medications can also cause teeth to become stained as they are developing.

How Does Professional Tooth Whitening Work?
Professional tooth whitening occurs by neutralizing tooth discoloration. As the carbamide peroxide in professional whiteners is activated, oxygen penetrates the hard outer surface of the tooth (enamel) and removes the underlying colored or stained substances. Since enamel itself is transparent, the natural, lighter color of the inner tooth will then show through.

How Do You Get Started?
The professional whitening procedure begins with a consultation in your dentist’s office. Your dental professional will make a custom impression of your teeth and form a tray to comfortably fit your mouth. Treatments are then completed at home.

How Long Will Your Teeth Stay White?
Professionally whitened teeth stay bright for an extended length of time. With periodic touch-up applications and regular dental hygiene visits, your whiter, brighter smile will last and last.

How Soon Will You See Results?
Most people will see an improvement within a few weeks. Simply follow the treatment schedule recommended by your dental professional, which is based on the condition of your teeth when you begin the procedure.

Should You Consider Having Your Teeth Professionally Whitened?
White & Brite™ Tooth Whitening Gel has been recommended by thousands of dental professionals since it was introduced over 10 years ago. Professional tooth whitening has been shown to be a safe and effective way for millions of people to obtain a whiter, brighter smile.

Summary

• Years of consuming coffee, tea, soda and other items gradually causes youthful, white teeth to discolor. Zaris’ White & Brite Tooth Whitening Gel can help bring back a whiter smile.

• Zaris White & Brite gel:
  • Whiten teeth with carbamide peroxide.
  • Does not require the use of reservoirs or blocking.
  • Provides noticeable whitening within a few weeks (10% and 16% strengths).
  • Provides long-lasting white teeth. Touch-up kits are also available.
  • 10% and 16% strength formulas are specially formulated for convenient at-home bleaching.
  • 30 gel is specially formulated for in-office, professionally supervised bleaching.
  • Comes with a convenient and hygienic tray storage case.
  • Was given the second-highest overall score when evaluated by an independent clinical research institute.¹

Warranty

3M ESPE warrants that Products are free of defects in material and manufacture at the time of shipment. 3M ESPE’s entire liability and user’s exclusive remedy under these warranties, shall be either to promptly replace defective units, or at 3M ESPE’s option, to refund the purchase price paid by user within a reasonable time after written notification of the defect and return of the defective product to 3M ESPE. Notice of defect must be received by 3M ESPE within 30 days after discovery of the defect by user not to exceed one year from the date of delivery.

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References


