



10% y 16%: 3 a 4 horas diario; 22%: 1 hora diario; Obs: Este protocolo podrá ser alterado mediante indicación del profesional. Generalmente para pacientes con hipersensibilidad elevada, se recomienda la utilización de los geles en periodos fraccionados en dos veces al día (ej: uso por 30min por la mañana y 30min por la noche) o en días alternados. Es interesante notar que, siguiendo el protocolo convencional, la media de duración de un aclaramiento es de 14 días. Caso el protocolo fuera alterado, un aumento en este periodo podrá ser esperado para alcanzar el punto de saturación de color de los dientes.

#### Cuidados con el Paciente

##### Hipersensibilidad Dental:

Antes de iniciar el tratamiento, se recomienda aplicar el producto Desensibilize KF 0,2% o 2% FGM en los dientes a ser aclarados, por 10 minutos en férula individual o con aislamiento relativo en el consultorio, respectivamente. La aplicación de este desensibilizante tiene el objetivo de reducir la intensidad de la hipersensibilidad dental durante el aclaramiento(1-3).

Para aclaramiento casero se sugiere uso de Desensibilize KF 0,2% en férula en los 03 primeros días del tratamiento, utilizando el desensibilizante por 10 minutos antes de aplicar el gel aclarador y, se necesario, por más 10 minutos después de la aplicación del aclarador. Paralelamente, se sugiere investigación clínica y radiográfica sobre las causas de la hipersensibilidad.

*1 Kose Jr, C.; Pereira, S.; Reis, A.; Loguercio, A. Evaluation of a Desensitizing Agent fo At-home Bleaching. J Dent Res 89 (Spec Iss B): 1426, 2010.*

*2 Paula, E.A.; Martins, G.C.; Pereira, S.K.; Gomes, O.M.; Loguercio, A.; Reis, A. In Office Bleaching: Effect of Preliminary Use of a Desensiting Agent. J Dent Res 89: 559, 2011.*

*3 Tay, L.Y.; Kose, C.; Andrade, T.M.; Loguercio, A.; Reis, A. Preventive Effect of a Desensitizing Gel Before In-office Tooth Bleaching. J Dent Res 88 (Spec Iss A): 2369, 2009.*

Informe al paciente sobre el tratamiento y discuta sus expectativas. Informe de que los dientes de cada persona tienen un potencial de aclaramiento diferente y que talvez no se obtenga el nivel de aclaramiento que imagina. Tome fotos o registre el color de los dientes antes y después del tratamiento para evidenciar los resultados.

- Informe al paciente que restauraciones no son aclaradas por el

producto y que tendrán que ser cambiadas después del tratamiento siempre que traigan impacto en la estética. Restauraciones adhesivas deben ser realizadas solamente de 7 a 14 días después de la conclusión

- del aclaramiento.
- Antes de iniciar el aclaramiento se debe realizar examen clínico y radiográfico del paciente para asegurarse de que los tejidos estén libres de caries e infiltraciones en restauraciones, que tengan tejidos gingivales saludables y que esté libre de otros problemas que puedan provocar hipersensibilidad durante el aclaramiento.
- Enseñe el paciente a colocar el gel en la férula. El exceso de gel debe ser evitado y removido con el auxilio de cepillo o el propio dedo. El contacto prolongado con la encía puede resultar en determinado grado de irritación.
- Informe el paciente que puede sentir un aumento de la sensibilidad de los dientes a variaciones de temperatura, principalmente al frío. Caso el paciente sienta demasiada incomodidad o presente alguna reacción alérgica al producto, se debe suspender el tratamiento y evaluar las causas antes de darle continuidad.
- Oriente el paciente a evitar la ingestión de bebidas o alimentos ácidos durante el tratamiento porque estos pueden causar aumento de la sensibilidad dental. Bebidas o alimentos fuertemente colorados también deben ser evitados, pues pueden comprometer el proceso de aclaramiento.
- Entregue al paciente la receta con instrucciones de uso y enfatice la importancia de su lectura. Oriéntelo a reportar cualquier incomodidad o reacción significativa que pueda presentar.

#### Conservación y Almacenamiento

Almacenar el producto en temperaturas entre 5 y 27 °C. No congelar el producto. Proteger de la incidencia de la luz solar directa.

#### Advertencias:

No utilizar el producto fuera del plazo de validez. Para el desecho del producto siga la legislación de su país. Mantener fuera del alcance de los niños.

Este material fue fabricado solamente para uso dental y debe ser manipulado de acuerdo con las instrucciones de uso. El fabricante no es responsable por daños causados por otros usos o por manipulación incorrecta. Además de esto, el usuario está obligado a comprobar,

antesdel empleo y bajo su responsabilidad, si este material es compatible con la utilización deseada, principalmente cuando esta utilización no está indicada en estas instrucciones de uso. Descripciones de datos no **Conservación y Almacenamiento**

Almacenar el producto en temperaturas entre 5 y 27 °C. No congelar el producto. Proteger de la incidencia de la luz solar directa.

#### Advertencias:

No utilizar el producto fuera del plazo de validez. Para el desecho del producto siga la legislación de su país. Mantener fuera del alcance de los niños.

Este material fue fabricado solamente para uso dental y debe ser manipulado de acuerdo con las instrucciones de uso. El fabricante no es responsable por daños causados por otros usos o por manipulación incorrecta. Además de esto, el usuario está obligado a comprobar,

#### EN Instructions for use

#### Dental bleaching for supervised home use

##### Only Professional Use

*Read carefully all the instruction manual information before using the product. Keep it for consultation, at least until total consumption of the product and/or until there is no more interaction of the product with your last patient.*

Besides this instruction manual, Whiteness Simple offers another handbook to the patient. It is recommended to hand over the referred handbook to the patient and explain it carefully at the beginning of the treatment. Observe that the document has a guiding purpose and professional recommendations to the patient are very important.

#### Product Description

Whiteness Simple is a dental bleaching gel with carbamide peroxide in concentrations of 10%, 16% or 22%.

For home application under supervision of a Dental surgeon. The Whiteness Simple formulation combines the high viscosity of the carbopol gel with the bleaching effect of carbamide peroxide to obtain the dental whitening efficacy. The pH of the gel is neutral in order to prevent decalcification of the enamel and dentin, and the addition of sodium

fluoride is intended to act as a desensitizing agent.

The product should be applied in individual tray during a period of 3-4h for 10% and 16% versions, and 1h to 22% version, making the most of the gel innings. On average, the treatment lasts about 14 days under standard protocol. However, the use of the gel is versatile and can be changed as appropriate by a professional guidance.

#### Display formats

10%, 16% and 22%.

**Kit:** Include 04 whitening gel syringes containing 3g each one, 04 tips for applying the gel, 2 vinyl plates 1mm thick for making the trays, 1 case for keeping the trays, and instructions to the patient and professional.

**Refill:** Contains 01 whitening gel syringe with 3g each and 01 tip for application.

**Bulk:** 30 syringes of whitening gel containing 3g each one or; 50 whitening gel syringes containing 3g each one.

#### Basic Composition

Active Ingredients: 10% 16% or 22% carbamide peroxide.

Inactive Ingredients: Carbopol, potassium hydroxide, sodium fluoride, glycerol, deionized water.

#### Indication of the product

This is a product for a dental professional use, for bleaching vital teeth. Intended for bleaching done at the patient's home (also known as home bleaching) and must be indicated and realized under the supervision of a dentist.

Indicated for the following cases:

- Vital teeth darkened by age (physiological darkening)
- Vital teeth naturally dark or yellow.
- Vital teeth which are darkened or discolored due to the incorporation of substances containing pigments such as coffee, tobacco, tea, etc.
- Stains with mild-to-moderate intensity due to fluorosis.
- Tetracycline-stained vital teeth, in cases which the staining is smooth.

#### Precautions and Contra-indications

The product must be properly indicated by a professional and the treatment should be accompanied until the conclusion.

Health check and radiographic examination should be performed in search of possible situations that may bring risks to the teeth during the dental bleaching: fissures/cracks important in enamel or dentin, cement or exposed dentin, dental decay, infiltration in restorations, defects in the

formation of enamel or dentin, severe fluorosis, intense staining tetracycline, gingivitis or periodontitis (with or without tooth mobility), periodontal bags, presence of endodontic problems (pulpitis, abscess or root resorption), ulcers in oral soft tissues, among other factors believed to affect the treatment's safety.

All the described conditions above should pass through a treatment before the beginning of dental bleaching, and if they are not fully resolved, the bleaching treatment is contraindicated.

Teeth with gingival recession should receive cement coverage by restorative materials in order to prevent direct contact with the whitening gel. During these cases, it is recommended to cut the tray on the edge of the cement-enamel junction to avoid prolonged contact of the gel with the exposed region.

Teeth with cracks or micro-cracks may have continuous or intermittent painful sensations and should also be treated previously.

Before beginning the treatment, it is recommended prior application of Desensibilize KF 0.2% or 2%.

If the patient has shown hypersensitivity, it is recommended to use less concentrated bleaching (10% carbamide) and / or changes the protocol of the use of bleaching alternating day gel application or dividing the daily period in two stages.

The gel application time can be softened according to the professional guidance. The gel has maximum periods of pre-defined activity, therefore the nighttime use of the same will not increase its efficiency.

Verify the adjustment and finishing of the tray. Too tight trays or burrs can bring gum damage. Usually, the cut of the tray should involve up until 1mm the marginal gingiva, making sure that all the cervical area of the tooth is covered.

Inform the patient to apply the gel in individual tray. Any excess of the gel should be removed with the fingers to avoid unnecessary contact with the gel gums and possible irritation.

Give to the patient the brochure with your instructions and emphasize the importance of its reading.

Inform to the patient that it is normal to feel mild dental hypersensitivity in the first days of treatment, either spontaneous or temperature difference. Still, the gums may present redness and be slightly sensitive to brushing. These symptoms should stop until the third or fourth day of treatment. If the discomfort is too much, stop treatment and investigate the cause.

For a proper progress of whitening teeth, tell the patient to refrain stained or acidic foods, or at least reduce their consumption. It is important to brush the teeth/ rinse mouth after any food intake.

Let the patient aware of the expected results: teeth with gray staining or

reason should receive prior treatment for bleaching treatment.

The supervision of treatment should be done through regular appointments, spaced 5-7 days. Emphasize to the patient that if he or she look for you if there is a problem during this period.

Gingival irritation can happen when there is using of mouthwashes or toothpastes with strong flavor before using the tray with gel.

It is recommended if the person wants to make use of these products, give a break of at least 30 minutes (or enough time to the disappearance of sensitivity) between the use of mouthwash or toothpaste and the gel use.

The aggressive brushing on the gums can also sensitize them and result in some irritation by the gel.

Teeth with cracks or micro-cracks may have continuous or intermittent painful sensations and should also be treated previously.

Before beginning the treatment, it is recommended prior application of Desensibilize KF 0.2% or 2%.

If the patient has shown hypersensitivity, it is recommended to use less concentrated bleaching (10% carbamide) and / or changes the protocol of the use of bleaching alternating day gel application or dividing the daily period in two stages.

The gel application time can be softened according to the professional guidance. The gel has maximum periods of pre-defined activity, therefore the nighttime use of the same will not increase its efficiency.

Verify the adjustment and finishing of the tray. Too tight trays or burrs can bring gum damage. Usually, the cut of the tray should involve up until 1mm the marginal gingiva, making sure that all the cervical area of the tooth is covered.

Inform the patient to apply the gel in individual tray. Any excess of the gel should be removed with the fingers to avoid unnecessary contact with the gel gums and possible irritation.

Give to the patient the brochure with your instructions and emphasize the importance of its reading.

Inform to the patient that it is normal to feel mild dental hypersensitivity in the first days of treatment, either spontaneous or temperature difference. Still, the gums may present redness and be slightly sensitive to brushing. These symptoms should stop until the third or fourth day of treatment. If the discomfort is too much, stop treatment and investigate the cause.

For a proper progress of whitening teeth, tell the patient to refrain stained or acidic foods, or at least reduce their consumption. It is important to brush the teeth/ rinse mouth after any food intake.

Let the patient aware of the expected results: teeth with gray staining or

affected by tetracycline staining may have an unsatisfactory response to bleaching. Explain also that each patient has a possible whitening degree because the individuality of dental physiology. The patient should also be aware that restorative materials (direct and indirect) not clear and devitalized teeth may need specific treatment (internal bleaching, restorations, etc.).

For documentation of the results, it is suggested periodic photographs of the case and recording of the evolution of the teeth color by a color scale, if possible, with the participation of the patient through a mirror.

For possible replacement of restorations, wait at least 7 days after the conclusion of bleaching for elimination of residual oxygen.

Amalgam restoration could bring local dimming of the custom tray, by the surface oxidation.

For diabetic patients, it is recommended that the disease is properly controlled before and during the using of bleaching to prevent any irritative effects of the product. As an alternative, consider in-office bleaching because it does not cause contact of the gel with the gingiva.

The use of the product is contraindicated for pregnant women, nursing mothers, people allergic to the components of the formula and people under 15 years old.

**Side effects**

Some patients may feel tooth sensitivity during the product use. This tooth sensitivity is usually mild to moderate and disappears in 1 or 2 days after stopping treatment. If the tooth sensitivity is more severe, the treatment should be discontinued and the cause must be treated before continuing treatment.

Some patients may feel some irritation in the throat due to the swallowing of larger amounts of whitening gel.

Dental bleaching can praise pre-existing enamel hypoplasia spots (opaque white spots).

Patients with sensitive, injured or ill health gums may have irritation caused by contact with peroxide.

#### Instructions for use

Before starting the treatment read carefully the Warnings, Precautions, Contraindications and possible Side Effects.

The bleaching gel should be used in individual trays of flexible acetate, applying a small amount (a "drop") in the space related to each tooth to be bleached. The concentration, running times and additional details are described below:

#### Selection of Concentrations

Simple whiteness is available at the following concentrations: 10%, 16% and 22%. In cases of normal pigmentation by age or by tobacco, coffee, or either when the tooth sensitivity manifests itself more strongly the gel using 10% is indicated. In the cases of increased pigmentation, the gel using 16% or 22% is indicated.

In cases of a tetracycline stains could be expected some improvement, depending on the severity of the stain. Longer treatment time is usually required for these cases.

#### Time of gel use

Based on the uptime of each concentration, it is recommended: 10% and 16%, 3 to 4 hours daily; 22%: one hour daily;

Note: This convention can be changed depending of the professional indication. Usually, patients with higher hypersensitivity is recommended to use the gels in fractionated periods twice a day (e.g., use for 30min at morning and 30 min at night) or on alternate days. It is interesting that, following the standard protocol, the average duration of a dental bleaching is 14 days. If the convention is changed, an increase in this period could be expected to achieve the color saturation point of the teeth.

#### Patient Care:

##### Dental hypersensitivity:

Before starting treatment, it is recommended to apply the FGM Desensibilize KF agent 0.2% or 2% in the teeth to be whitened for 10 minutes in individual tray or in relative isolation in the office, respectively. The application of desensitizing aims to reduce the intensity of dental hypersensitivity during the bleaching. (1-3)

For home bleaching it is suggested the use of 0.2% by KF Desensibilize tray during the three first days of treatment, using the desensitizing for 10 minutes before applying the bleaching gel and, if necessary, for another 10 minutes after the application of the whitener.

Simultaneously it is suggested clinical and radiographic investigation into the causes of hypersensitivity.

*1 Kose Jr, C.; Pereira, S.; Reis, A.; Loguercio, A. Evaluation of a Desensitizing Agent fo At-home Bleaching. J Dent Res 89 (Spec Iss B): 1426, 2010.*

*2 Paula, E.A.; Martins, G.C.; Pereira, S.K.; Gomes, O.M.; Loguercio, A.; Reis, A. In Office Bleaching: Effect of Preliminary Use of a Desensiting Agent. J Dent Res 89: 559, 2011.*

*3 Tay, L.Y.; Kose, C.; Andrade, T.M.; Loguercio, A.; Reis, A. Preventive Effect of a Desensitizing Gel Before In-office Tooth Bleaching. J Dent Res*

*88 (Spec Iss A): 2369, 2009.*

• Advise the patient about the treatment and discuss his or her expectations. Tell him or her that each person teeth has different whitening potential and that he or she may not get the level of whitening them could think. Take pictures or record the color of the teeth before and after treatment to evidence the results.

• Inform the patient that restorations are not bleached by the product and they will always have to be exchanged after treatment when shocked aesthetics happen. Bonded restorations must be treated only 7 to 14 days after completion of bleaching.

• Before beginning the treatment, the patient should be examined clinically and radiographic aspects to ensure that the teeth are free from cavities and infiltrations in restorations, exam if have healthy gingival tissues and is free of other problems that may cause hypersensitivity during bleaching.

• Teach the patient to put the gel in the tray. The excess gel should be avoided and removed with the aid of brush or with own fingers. Prolonged contact with the gums can result in some irritation degree.

• Inform the patient that he or she may experience increased tooth sensitivity depending of temperature changes, mainly when it is cold. If the patient feels too uncomfortable or have an allergic reaction to the product, it should discontinue treatment and check the causes before continuing the treatment.

• Advice the patient to avoid the intake of acidic foods or beverages during treatment because they can cause increased tooth sensitivity. Beverages or strongly colored foods should also be avoided as they may compromise the whitening process.

• Give the patient the handbook with instructions for use and emphasize the importance of reading. Advise him or her to report any discomfort or significant reaction that he or she may have.

#### Confectioning of the Trays:

- Molding;
- Casting in plaster;
- Vacuum -Forming;
- Trimming.

#### Conservation and Storage

Store the product at temperatures between 5 and 27 ° C. Do not freeze the product. Protect from direct sunlight.

#### Warnings:

Do not use the product if it is out of shelf life. Follow the laws of your

country for the product disposal. Maintain outside the reach of the children.

This material was developed only for dental use and must be handled according to the instructions. The manufacturer is not liable for damages caused by other uses or incorrect handling. In addition, the user must prove, before the use and under his or her responsibility if this product is compatible with the desired utilization, especially when this use is not indicated in these operating instructions. Data descriptions do not constitute any type of guarantee.

• Before beginning the treatment, the patient should be examined clinically and radiographic aspects to ensure that the teeth are free from cavities and infiltrations in restorations, exam if have healthy gingival tissues and is free of other problems that may cause hypersensitivity during bleaching.

• Teach the patient to put the gel in the tray. The excess gel should be avoided and removed with the aid of brush or with own fingers. Prolonged contact with the gums can result in some irritation degree.

• Inform the patient that he or she may experience increased tooth sensitivity depending of temperature changes, mainly when it is cold. If the patient feels too uncomfortable or have an allergic reaction to the product, it should discontinue treatment and check the causes before continuing the treatment.

• Advice the patient to avoid the intake of acidic foods or beverages during treatment because they can cause increased tooth sensitivity. Beverages or strongly colored foods should also be avoided as they may compromise the whitening process.

• Give the patient the handbook with instructions for use and emphasize the importance of reading. Advise him or her to report any discomfort or significant reaction that he or she may have.

#### Confectioning of the Trays:

- Molding;
- Casting in plaster;
- Vacuum -Forming;
- Trimming.

#### Conservation and Storage

Store the product at temperatures between 5 and 27 ° C. Do not freeze the product. Protect from direct sunlight.

#### Warnings:

Do not use the product if it is out of shelf life. Follow the laws of your