



DSP WHITE CLINIC

MANUFACTURED AND DISTRIBUTED BY:



DSP Industrial LTDA | CNPJ: 03.960.018/0001-23

Rua Marechal Floriano Peixoto, 303 Ouro Verde II - Campo Largo - PR 83.606-290
- SAC 0800.600.88.66

Resp. Técnico: Célio G. Netzel
CREA-PR: 25412/D

Anvisa Registration: 80116989007

FOR PURCHASES, QUESTIONS, COMPLIMENTS, AND COMPLAINTS: 0800 600 8866

INSTRUCTIONS FOR USE | english

TRADE NAME: DSP White Clinic

TECHNICAL NAME: Dental Whitening Agents

CÓDIGO: 0.5000

Please read all information of this instruction for use carefully before applying the product.

DENTAL WHITENER FOR CLINICAL USE.

FOR HOME APPLICATION UNDER THE SUPERVISION OF A DENTAL SURGEON

SALE UNDER PRESCRIPTION (ACCORDING TO RDC NO. 923 OF 2024)

Keep for consultation until the total consumption of the product. Keep this instruction until there is no more interaction of the product with your patient.

CONTENT:

Kit with gingival barrier:

- 1 bottle of Hydrogen Peroxide with 15g,
- 1 bottle of Thickener with 5g,
- 1 bottle of 10g Peroxide Neutralizer,
- 1 syringe DSP Dam gingival barrier with 2g with 2 applicator tip,
- 1 mixing container for preparing the gel,
- 1 spatula,
- 1 instruction manual for the professional.

PRODUCT DESCRIPTION:

DSP White Clinic 35% H₂O₂ is a professional dental whitening system based on 35% Hydrogen Peroxide for whitening of vital and non-vital teeth, for exclusive use in the dental clinic. And it should always be used with an efficient isolation system for gingival protection (DSP Dam light-cured gingival barrier). After homogeneous blending of the two phases, they form a gel based on 35% Hydrogen Peroxide, with pH

DSP WHITE CLINIC

in the range 6.0 to 7.0, being considered a neutral pH to avoid and decrease effects on the dental structure and that contains desensitizing agents in its formula that maximize the patient's comfort. The action of whitening agents is related to their penetration into dental structures (enamel and dentin) reacting with the pigmented molecules, oxidizing them and making them simpler and less pigmented, causing the pigments incorporated into the tissues to be totally or partially eliminated from the dental structure.

PRODUCT INDICATION:

DSP White Clinic 35% H₂O₂ was developed with the highest technology on the market and is indicated for vital and non-vital teeth with extrinsic color changes of a chronic nature, not susceptible to removal by conventional procedures for exclusive use in the dental clinic. It is not necessary to apply a light source as an additional method to accelerate the lightening process. The product will act effectively even in the absence of photoactivation.

COMPOSITION:

Hydrogen Peroxide 35%, Thickeners, neutralizers, mixture of dyes, glycols and Deionized Water.

INSTRUCTIONS FOR USE:

1st step

Select and record the color of the patient's teeth using a color scale and/ or photograph before starting whitening.

2nd step

Perform the relative isolation with DSP dam (lightcured gingival barrier) covering the marginal gingiva and papillae with a layer of 3 to 5 mm wide and a maximum of 1 mm thick. The gingival barrier should cover approximately 0.5 to 1 mm of the dental surface. Notes: Use a clinical mirror looking from incisal to cervical and observe for uncovered gingival tissue. If so, perform the correction. This step is crucial to avoid contact of Hydrogen Peroxide with the gum. Use a lip

retractor to facilitate the application of the gingival barrier and also the whitener.

3rd step

Polymerize the light-cured gingival barrier DSP Dam using 20 to 30 seconds of light curing for each group of 3 to 4 teeth. The gingival barrier that forms is rigid and insoluble, preventing possible irritation by aggressive products.

4th step

Using the mixing plate that comes with the kit, mix the Peroxide phase (phase 1) with the Thickener phase (phase 2) in the ratio of 3 drops of Peroxide to 1 drop of Thickener. The mixture of 3 drops of Peroxide to 1 drop of Thickener is sufficient for an application on a tooth. For smile line (20 teeth) usually 12 drops of peroxide for 4 drops of Thickener are sufficient. Shake the Thickener bottle vigorously before use.

5th step

With the aid of a brush or spatula, fully cover the vestibular surface of the teeth to be whitened, including the interproximal teeth and extend a little on the incisal and occlusal faces. The gel layer should be between 0.5 and 1mm thick.

6th Step

Each application of the gel should last 10 to 15 minutes. With the help of a brush or micro applicator, move the gel over the teeth three to four times to release any oxygen bubbles generated and renew the best possible contact of the gel with the teeth.

7th Step

At the end of the recommended time, suck the gel over the teeth with a vacuum cannula and clean them with a gauze to get them ready to receive a new portion of gel. Repeat steps 4 to 6 up to two more times in the same session, if necessary according to the evolution of the results and monitoring of the patient's sensitivity.

8th Step

Remove the gingival barrier by highlighting it forward.

9th Step

Apply Desensitizing DSP Desensitizer 2% NaF for 10 minutes. After 24 hours, it is suitable to do the final polishing of the teeth with diamond polishing paste, DSP Diamond Polishing. Check the final appearance after treatment. Perform a comparison with the start and end photo.

Notes: • Monitor the patient throughout the whitening with respect to dental sensitivity and possible points of peroxide irritation. If there are any of these cases, interrupt the process and perform a verification and intervention (see comments in the section Precautions and Side Effects). • If the obtained whitening does not meet the expectation and if the patient does not present sensitivity or other

contraindication, the reapplication of the product can be done for up to two more sessions. If more than one session is required, a minimum interval of 7 days should be given between sessions.

Whitening of Non-Vital Teeth

Before starting the whitening, x-ray the tooth to be whitened to verify its condition. Treatment should be within acceptable endodontic standards.

1st step

Select and record the color of the patient's teeth using a color scale or photograph before starting whitening.

2nd step

Perform a good coronary opening by removing present restorations, carious dentin, etc. With the pulp chamber clean, deepen the entrance of the conduit by removing approximately 3mm of filling to perform the sealing of the channel (the sealing prevents the diffusion of the whitening agent to the cementum and periodontium region. It is recommended that the channel be sealed with glass ionomer in a minimum thickness of 2mm for better sealing).

3rd step

Isolate the teeth with the DSP Dam light-cured gingival barrier and mix the DSP White Clinic 35% H₂O₂ whitening phases in the proportion of 3 drops of phase 1 (peroxide) to 1 drop of phase 2 (thickener). Shake the Thickener bottle vigorously before use.

Shake the Thickener bottle vigorously before use.

4th step

Apply DSP White Clinic 35% H₂O₂ on the vestibular face and inside the pulp chamber with the help of a brush. A layer approximately 1mm thick is enough.

5th Step

Remove the gel using a suction cannula before reapplying the product. Up to three gel applications can be made in the same session. After completion of the whitening agent applications, wash and dry the tooth. Temporarily restore the cavity and follow the whitening result for at least one week. If necessary, repeat the applications up to 4 times.

Notes:

The temporarily restored non-vital tooth presents the crown weakened by the absence of dental structure inside. Instruct the patient to take due care not to fracture the fragile tooth crown.

After removing the DSP White Clinic 35% H₂O₂, you can use the DSP White Endo Gel whitener (35% Carbamide Peroxide for internal use) and continue the tooth whitening during the interval between

sessions with DSP White Clinic 35% H₂O₂(for use of the DSP White Endo Gel whitener see its specific instructions for use)

6th Step

At the end of the entire whitening process, definitively restore the whitened tooth. It is recommended to wait a minimum of 7 days before restoring (time for stabilization of tooth color and elimination of residual oxygen).

Check the final appearance after treatment. Perform a comparison with the start and end photo.

PRECAUTIONS:

Before Whitening

- Promote a detailed medical history.
- The patient should have a perfectly clean tooth surface and no calculus.
- The gums should be healthy without inflammation.
- Prophylaxis with water and pumice stone, not using sodium bicarbonate.
- Perform removal of calculus at least 2 days before whitening.
- If the patient has spontaneous sensitivity in the teeth, treat it before whitening.
- If the teeth to be whitened present gingival retraction, isolate the area with the DSP dam.
- Ensure that the teeth to be whitened do not contain cavities or infiltrations in the restorations.
- In case of teeth with small fracture or incisal wear, protect the area with DSP Dam before application of the whitening gel to avoid sensitivity.
- All gingival tissue adjacent to the teeth must be protected with the DSP dam.

Upon Whitening

- Avoid contact of the gel with the soft tissues. If contact occurs, apply NEUTRALIZER.
- If the patient has sensitivity, the whitening can be interrupted after careful analysis by the professional.
- After application of the whitening gel, use the DSP Desensitizer 2% NaF and let it act for 3-5 minutes and polish with felt discs on the DESENSITIZER.

PRECAUTIONS AFTER WHITENING

- Do not smoke for at least 2 days.

- Do not ingest acid foods and soft drinks.
- For 24 hours do not ingest products containing dyes.
- Make use of white toothpaste and without sodium bicarbonate.

CONTRAINDICATIONS:

- The product is not indicated for whitening in pregnant women, infants and patients under 15 years of age.
- Patients with periodontal pathologies.
- Patients with incomplete root formation.
- Patients with allergic reaction to the product components.

GENERAL SAFETY INSTRUCTIONS:

- The product must be handled exclusively in the dental clinic.
- Wear gloves during the procedure.
- Wear safety goggles on the patient and the professional.
- Protect the lips with insulators such as petroleum jelly or similar.
- The contents of the peroxide bottles may be under pressure and/or may have leaked due to adverse storage conditions. Before opening the packaging, protect your hands and eyes and ensure that there is no leaked liquid inside.
- Avoid contact of the product with skin, mucous membranes or clothing.
- Do not ingest the product.
- In case of accidental contact with the skin or intraoral mucosa, the region should be cleaned with plenty of water. In these cases, the action of the whitening gel can be neutralized by covering the affected area with a few drops of the NEUTRALIZING solution.
- In case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice. Leftovers or residues from used materials should not be reused. Discard properly.

SIDE EFFECTS:

Some patients may experience dental sensitivity during or after whitening. If the patient has sensitivity during treatment, stop whitening and treat the teeth with desensitizing agent DSP Desensitizer 2% NaF. If the sensitivity persists and it is not possible to continue the whitening, schedule a new session with a minimum interval of 7 days. Assess whether there are any anomalies in the teeth that can be corrected to eliminate such sensitivity. There are cases where sensitivity appears only after treatment (1 or 2 hours after). In these cases, if the sensitivity is high, it is recommended to prescribe an analgesic and, eventually, an anti-inflammatory, according to the need of each case. Whitening may enhance pre-

existing areas of hypocalcification (hypoplasias) due to the different (more intense) whitening behavior of these areas. In some cases, these spots disappear due to the dehydration of the enamel after the whitening is complete. Fluoride treatment of these regions can also help in their disappearance. Discontinue use of the product in case of allergic reactions.

CONSERVATION AND STORAGE:

Keep the product in its packaging always closed.

Protect from the incidence of direct sunlight.

Store the product at temperatures from 0°C to 30°C.














If they find malfunctions, request the replacement of the material.

DATE OF MANUFACTURE: PACKING

EXPIRATION DATE: 2 YEARS AFTER THE DATE OF MANUFACTURE.

WARNING:

Respect the expiration date. Never use the product if it has expired. Keep out of reach of children. For dental use only. Before using observe the appearance of the product, if you notice any anomalies, contact the manufacturer or a professional immediately. The manufacturer is not responsible for damages caused by other uses or by incorrect handling. This material has been manufactured for dental use only and must be handled according to the instructions for use. It is the responsibility of the user to prove, before the use of this product, that this material is compatible and suitable for the desired use, especially when this use is not indicated in these instructions for use. Data descriptions do not constitute any kind of guarantee and, therefore, do not have any link. Do not reuse empty packages. Do not reuse empty packaging for other purposes. To dispose of the product, follow local legislation.

	Code of Product
	Number of the lot
	Manufacturer
	Date of manufacturing
	Representative in the community european
	Prohibited Reprocess
	Date of Durability Minimum
	Do not reuse
	Do not use if the package it's damaged
	Keep Dry
	Keep away from light
	Notification demanded by FDA for Business In the USA
	Reference to information join or attached