Crystal Clear Whitening®

Professional Teeth Whitening Gel

Formula: 6% Hydrogen Peroxide

Version: 1.0

Date: 2026-04-08

Confidential — Internal Use Only

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1. Overview

Crystal Clear Whitening® is a professional-grade, chemical-free teeth whitening gel formulated with 6% hydrogen peroxide. It is designed for use in dental offices and by trained professionals as part of a controlled whitening protocol. The product is supplied in a single-use syringe and applied directly to the teeth by the operator.

2. Intended Use

Intended use: Professional teeth whitening in dental offices and by trained professionals.

Not for: Self-administered whitening, sale to consumers, use on children under 18, use on teeth with active caries or gum disease.

3. Ingredients

Ingredient	Role
Hydrogen Peroxide 6%	Active whitening agent
Glycerin	Humectant, viscosity modifier
Purified Water	Solvent
Carbomer	Gel thickener
Potassium Nitrate	Desensitizer
Sodium Hydroxide	pH adjuster
Phosphoric Acid	pH adjuster
Sodium Saccharin	Sweetener
Peppermint Oil	Flavor
Polysorbate 20	Surfactant
Citric Acid	pH adjuster
Sodium Benzoate	Preservative
Tetrasodium EDTA	Chelating agent

4. Mechanism of Action

Hydrogen peroxide (H₂O₂) decomposes on contact with tissue and saliva to release free radicals (primarily hydroxyl and perhydroxyl radicals) and nascent oxygen. These reactive species oxidize chromogenic compounds in the enamel and dentin, breaking down the molecules responsible for tooth discoloration. The potassium nitrate component reduces nerve sensitivity during and after treatment.

5. Physical Properties

Appearance	Clear, colorless gel
Viscosity	Thixotropic
pH	3.5 – 4.5
Density	~1.1 g/cm³
Odor	Mild peppermint

6. Stability Profile

Shelf life	24 months
Storage	15–25 °C, dry place
Light sensitivity	Yes — keep out of direct sunlight
Freeze–thaw	Not recommended

7. Manufacturing Process

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1. Purified water is charged into the mixing vessel and heated to 60–70 °C.
2. Glycerin and carbomer are added and mixed until a homogeneous gel base is formed.
3. Potassium nitrate, sodium saccharin, and tetrasodium EDTA are added and dissolved.
4. Hydrogen peroxide is added last, at ambient temperature, to minimize early decomposition.
5. pH is adjusted with phosphoric acid and sodium hydroxide to target 3.5 – 4.5.
6. Peppermint oil and polysorbate 20 are added and mixed.
7. Bulk gel is filtered and transferred to the filling line.
8. Filled syringes are sealed, labeled, and released after QC sign-off.

8. Quality Control

Test	Specification
Appearance	Clear, colorless gel
pH	3.5 – 4.5
Viscosity	Thixotropic
Hydrogen peroxide content	5.7 – 6.3 %
Peroxide decomposition	Not accelerated
Microbial limits	Per USP <61>
Fill weight	Per specification

9. Packaging

Primary: Single-use syringe, 1.2 g gel per syringe.

Secondary: Carton with 10 syringes.

Tertiary: Shipper box, 100 syringes (10 cartons).

10. Regulatory Status

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11. Safety Profile

Mild: 70%
Moderate: 20%
Severe: 10%

Mild reactions are most commonly reported and include transient gingival irritation and tooth sensitivity. Moderate reactions include persistent sensitivity and gingival inflammation. Severe reactions are rare and include chemical burns to the gingiva when the product is applied improperly or in excess.

12. Storage & Handling

- Store at 15–25 °C in a dry place.
- Keep out of direct sunlight.
- Do not freeze.
- Keep syringes upright to prevent gel settling.
- Dispose of unused syringes in accordance with local regulations.

13. Revision History

Version	Date	Change
1.0	2026-04-08	Initial release