

Hydra Pearl⁺

At-Home Whitening System

Instructions for Use

Description:

Hydra Pearl™ is a professional at-home tooth whitening system, containing 4 three-dose syringes of 6% hydrogen peroxide (pH ~5) whitening gel. This clear, flavored gel is formulated to remove discolorations due to food, stain-causing beverages, and tobacco products, without causing tooth hypersensitivity.

Procedure for Use:

1. Customize thermofitting trays

- 1) Place an unformed tray over your upper teeth and practice sucking air from the tray with your tongue against the roof of your mouth and the inside of the tray.
- 2) Heat a small pot of water to 80 °C or 180 °F
 - This can be done by bringing the water to a boil, removing it from the heat, and waiting a minute or two.
 - If a stove-top is not available to you, microwave a cup containing at least 4 inches of water for 2-3 minutes on HIGH. (10-15 oz. of water is suggested)
- 3) Hold one tray by the tab and lower it into the hot water. Keep it submerged for at least 6 seconds.
 - **⚠ CAUTION: Be careful to avoid skin contact with water, contact can cause burns immediately.**
 - Tray should be lowered vertically and held still in the water; **the sides of the tray must not touch each other.** If the tray folds in on itself, it cannot be reformed or used to whiten teeth.
 - The tray should wilt (start to visibly lose its shape) as you lift it vertically from the water. (If tray does not wilt or lose its shape, the water is not hot enough)
 - **DO NOT let the sides of the tray touch each other.**
- 4) Carefully and quickly place the tray over your upper teeth, and **immediately** suck the air from the tray. Continue to do this until you feel the tray cool slightly and become firm. (It may help to press the tray against the front of your teeth with your fingers and the back of your teeth with your tongue)

- 5) You should be able to see a visible print of your teeth in the tray when you remove it. If you are not satisfied with the fit of the tray, you can reheat and mold each tray many times.
- 6) Once you are satisfied with the fit, cut the front tab off of the tray with scissors.
 - Make the cut as close to the front surface of the tray as possible to minimize discomfort from the remains of the tab rubbing against gums.
 - You can also trim around the impressed gum-line if there is excess material that might cause discomfort after continual use.
- 7) Repeat steps 1-6 with the second tray for your bottom teeth.

2. Treat teeth with Hydra Pearl™ whitening gel

- 1) Before whitening, it is important to brush and floss your teeth gently and rinse your mouth with warm water.
- 2) Find your current tooth shade by matching your teeth to the shade guide included in the Hydra Pearl™ system.
- 3) Snap off tip of syringe needle. The removed tip should be flipped upside down, and used as syringe tip cover.
- 4) Place a small amount of Hydra Pearl™ gel in the trays for each tooth that needs to be whitened. **DO NOT overfill.** Use one measured dose or less (if preferred) to fill both top and bottom trays. Each syringe has enough gel for three treatments.
- 5) Place the gel-filled tray over the teeth. Gently suck on your teeth to create a suction to set the tray in place.
- 6) If the gel oozes out of the tray during placement, wipe away the excess gel. Make sure to remove all gel from your gums and gum line before and during each treatment.
- 7) Wear the trays for 15 minutes. Do NOT drink any liquids or eat food during the treatment. Do NOT wear the whitening trays overnight.
- 8) At the end of the treatment time, remove the trays. Rinse your mouth with water, and if needed, brush your teeth. Rinse the trays with cold water. Place the trays in the protective case and store in a cool, dry place.
- 9) It is highly recommended that you refrigerate the whitening gel between treatments. If left at room temperature, the strength of the whitening gel may decrease over time.

Note: Treated teeth will be visibly lighter after 3-5 treatments. You can continue to whiten your teeth until your desired shade is reached. Teeth will be maximally white after 10 treatments.

Gum Irritation:

Prolonged gel contact with gums or soft tissue may cause gum irritation. Gum tissue may turn white during treatment. This will fade in a few hours following the treatment. This is no cause for concern.

To prevent irritation:

- After placing trays over teeth, make sure excess gel has been removed.
- You may use less gel in the following treatments to avoid gum irritation.

Tooth Sensitivity:

Whitening treatments can cause tooth sensitivity among some patients.

To minimize sensitivity:

- Your dentist may recommend toothpaste for sensitive teeth to be used before or during the treatment period.
- Try whitening every other or third day if sensitivity continues.
- Avoid hot or cold beverages 30 minutes after treatment.
- Foods and drinks containing citric acid can cause sensitivity.

Sensitivity usually disappears within 1-3 days after treatment has ended. If you experience more than mild tooth sensitivity, discontinue treatment and consult your dentist.

White Stains:

White stains are usually caused by hypocalcification, not tooth whitening. However, whitening may make hypocalcified area appear much whiter. For patients, you may consult your dentist for options to remove white spots. For dental professionals, prior to bleaching a patient's teeth, we suggest you to closely examine areas of enamel thinning, chemical erosion, hypocalcification or chalky white spots. Please notify your patient that these white spots may become more apparent after whitening treatment.

Precautions:

- DO NOT use if pregnant or nursing
- Keep out of reach of children
- Adult supervision is recommended for patients ages 12-16
- DO NOT swallow gel (contains: hydrogen peroxide and sodium fluoride)

Notes:

- Drinking dark, staining substances within 24 hours of a treatment such as coffee, tea, red wine, and cola can stain your teeth and can make the whitening process take longer.
- Some amalgam/silver fillings can stain your whitening tray. This is no cause for concern.
- Crowns, bridges, partial dentures, veneers, and composite fillings will not whiten.
- Store whitening gel out of sun and heat. Refrigeration is recommended. DO NOT freeze.

Material Safety Data Sheet

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Division: Dental Consumables

Trade Name: Hydra Pearl 6% hydrogen peroxide whitening gel

ID Number: PD-R-953-001

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1. Ingredient

Chemical Name	C.A.S No.	Percent
Water	7732-18-5	35~46
Glycerin	56-81-5	30~40
Hydrogen peroxide	7722-84-1	4~7
Citric acid	77-92-9	2~5
Potassium nitrate	7757-79-1	0.5~1.5
Sodium fluoride	7681-49-4	0.1~1
Flavor	-	0.05~1.0

2. Physical Properties

Specific physical form	Gel
Odor	Flavor dependent
Color	Clear or slightly cloudy
Boiling point	N/D
Specific gravity	3.0
Viscosity	Approximately 20000 centipoises
Solubility in water	Partially soluble

3. Fire and Explosion Hazard Data

Flash point	N/D
Flammable limits - LEL	N/A
Flammable Limits - UEL	N/D
Extinguishing Media	Water spray, carbon dioxide, foam

No special firefighting procedures

No unusual fire or explosion hazards are anticipated

NFPA Hazard Codes: Health: 1 Fire: 1 Reactivity: 0

4. Reactivity Data

Stability	Stable
Conditions to Avoid	Heat, strong light
Incompatibility (Materials to avoid)	Strong acid, strong base, oxidizing agent
Polymerization	Not applicable
Hazardous Decomposition products	N/A

5. Environmental Information

Spill Response:

Wipe up small amounts with a chemical resistant or damp rag that is washed with large amounts of water after each use. After cleaning, flush away traces with water.

Recommended Disposal:

Dispose in accordance with national and local regulations.

Environmental Data:

N/A

Regulatory Information:

Safety, health and environmental regulations/legislation specific for the substance or mixture RoHS: Please refer to regulation 1223/200 on Cosmetics.

Regulations may vary; consult applicable regulation or authorities before disposal. In the event of an uncontrolled release, the user should determine if the quantity released qualifies as reportable.

6. Suggested First Aid

Eye contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Skin contact:

After contact with skin, wash immediately with plenty of water.

Ingestion:

Drink lots of water. Do not induce vomiting. Consult a physician if ingested in large amounts.

Inhalation:

Move to fresh air. If not breathing, give artificial respiration or oxygen by trained personnel. Seek immediate medical attention.

7. Precautionary Information

Eye protection:

Avoid eye contact with vapor, spray, or mist. Safety glasses with side shields are recommended.

Skin protection:

Avoid skin contact. Wear nitrile gloves when handling large amounts of this material. If skin contact occurs, wash with soap and water.

Ventilation Protection:

Do not handle large amounts of this material in a confined area or areas with limited air circulation.

Respiratory Protection:

Avoid prolonged breathing of vapors.

Prevention of Accidental Ingestion:

Do not eat, drink, or smoke when utilizing this product. Wash exposed areas thoroughly with soap and water. Wash hands between handling and eating. Do not ingest.

Recommended Storage:

Store in a cool place, away from acid, heat, and light.

Fire and Explosion Avoidance:

Keep caps on syringes when not in use.

8. Health Hazard Data

Eye Contact:

Mild eye irritation: signs/symptoms can include redness, swelling, pain, and tearing.

Skin Contact:

Allergic skin reaction: signs/symptoms can include redness, swelling, blistering, and itching.
Mild skin irritation: signs/symptoms can include redness, swelling, whiteness, and itching.

Inhalation:

No adverse health effects are expected from inhalation exposure.

Ingestion:

Swallowing a relatively large amount of this material is unlikely to produce serious illness or death.

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