

FLOR-OPAL SUSTAINED-RELEASE FLUORIDE- sodium fluoride gel
Ultradent Products, Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Flor-Opal®
Sustained Released Fluoride Gel

Description

Flor-Opal® is a unique, sustained-release, 0.5% fluoride ion in a sticky, viscous gel to be used with a custom tray. Flor-Opal is a clear, nearly tasteless, high-viscosity sticky gel with a pH of ~6.5.

Indications

Flor-Opal is designed for use whenever topical fluoride application is desired via take-home tray (e.g., prevention of root caries, treatment of periodontal conditions, following bleaching procedures, root sensitivity).

Procedure

1. Read and understand instructions before using or dispensing to patients.
2. Fabricate tray to meet patient's needs. See laboratory instructions (page 2) or send the working cast/model and prescription order form to Ultradent. Areas of sensitivity should be indicated on the cast before sending the model. If patient already has a custom bleaching tray, instruct them to apply Flor-Opal in the same manner as the bleaching gel.
Note: Trays made only for Flor-Opal may be constructed without scalloping; however, one should scallop trays made for Opalescence® bleaching.
3. Flor-Opal is dispensed in 1.2ml unit dose syringes. An application of a complete arch should use most of the contents of one unit dose syringe. Tray is loaded by running gel on underside of occlusal and incisal areas.
4. The length and number of times the tray is worn depends on the condition, the patient, and the clinician. Recommended treatment times generally range from 2 to 8 hours. Wearing the tray at night may be suggested since the gel generally stays active in the tray 8-10 hours because of slower muscle and salivary activity at night. Gel usually lasts 4-6 hours with daytime activity.

Ultradent Products, Inc.
Attn: Tray Fabrication
505 West 10200 South
South Jordan, Utah 84095

5. Tray should be removed at meal times. Following tray removal, patient should brush and rinse with water. DO NOT swallow solution during rinsing. Wash tray and store in a tray storage case. Fresh gel should be used for each application.
6. Gel may be warmed before placing in tray to avoid thermal sensitivity.

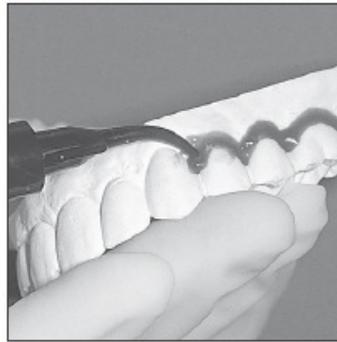


Fig. 1

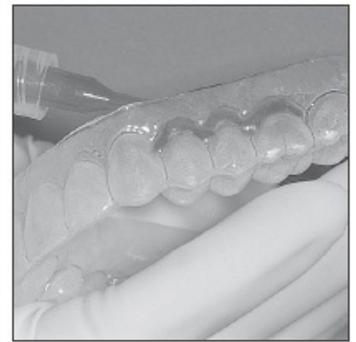


Fig. 2

Laboratory Instructions

1. Pour and trim cast as you would for a standard bleaching tray. Apply 0.5-1.0mm of Ultradent® LC Block-Out Resin to a clean, dry cast.
2. Cure LC Block-Out for ~2 minutes in a light curing unit. A hand-held intraoral light (Ultra-Lume®) can be used (approximately 20-40 seconds per tooth). Wipe off oxygen inhibition layer.
3. With vacuum former (Ultra-Form® or EconoForm™), heat a Sof-Tray® sheet until it sags ~1 inch. Activate vacuum and adapt softened plastic over mold. Cool and remove model.
4. Cut excess bulk of material away with Ultra-Trim™ scalloping scissors.
5. Trim excess tray material. Contour the tray margin to avoid frenum attachments, tori, and similar anatomical structures.
6. Return tray to model; check tray extensions. Gently flame polish edges one quadrant at a time (Blazer® Micro Torch).
7. While still warm, hold periphery of each segment firmly against model for 3 seconds with watermoistened finger. If an area is short of the desired length, gently heat and push the tray material to the desired location. If this material thins too much, a new tray should be fabricated.

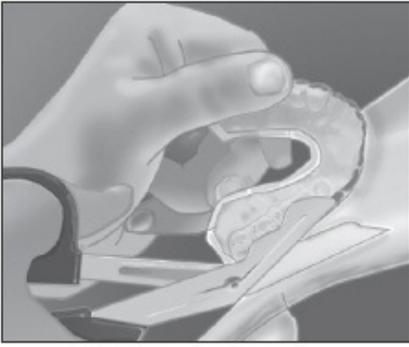
Precautions

1. If any problems occur, have the patient discontinue treatment and notify the dentist.
2. Patients should not swallow large volumes of Flor-Opal gel. Excess at insertion and residue upon removal should be brushed off and rinsed; DO NOT swallow.
3. Keep out of heat and sunlight at all times. Flor-Opal should be stored at room temperature.
4. Not intended for use by pregnant women.

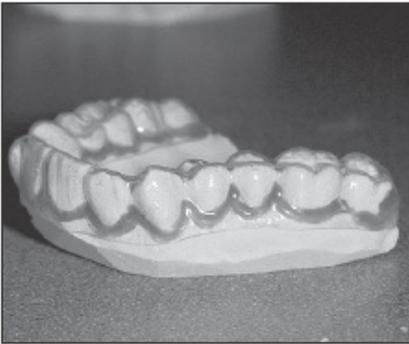
EN- DENTIST INSTRUCTIONS & LAB INSTRUCTIONS



Construct and dry the stone model, cutting palate and tongue areas out.



Vacuum adapt Sof-Tray® .035" sheet to model. Cool and separate.



For sensitive roots use Ultradent's LC Block-Out Resin on gingival margin to provide a reservoir space for Flor-Opal. It is recommended to lap tray 2-3mm onto gingiva.

General Precautions

1. For professional use only.
2. Review instructions, precautions, and MSDS before beginning treatment. Use only as directed.
3. Keep products out of heat/sunlight.
4. Avoid skin exposure to resins.
5. Isolate strong chemicals to area of treatment.
6. Confirm that patient has no known allergies to treatment materials.
7. Test flow of materials from syringe and tip before using intraorally.
8. Never force syringe plungers.
9. Clean and disinfect syringes between patients.

EN- PATIENT INSTRUCTIONS



Load gel into your bleaching tray made by your dentist. Use 1/3 to 1/2 of syringe.



Brush teeth, then insert tray. Adapt tray sides to teeth.



Remove excess gel with clean finger or soft toothbrush. Rinse twice; do not swallow rinses.



Clean tray with soft brush and cool tap water. Store tray in case provided.

Legend:



Use by date



See instructions



Batch Code



Keep out of reach of children



Recommended Storage Temperature



EN Toxic

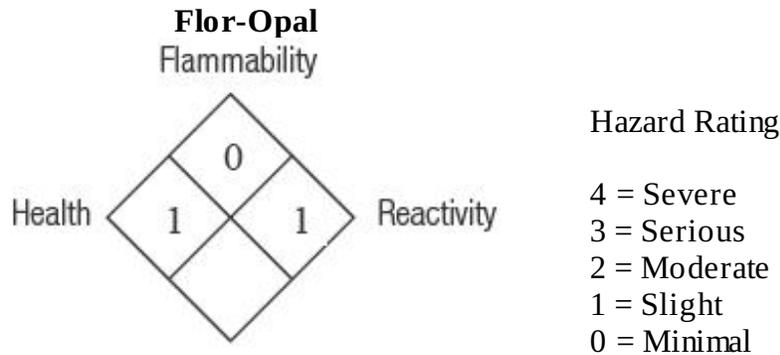


EN For Professional use only.

Not for injection.

Ultradent syringes have an expiration date stamped on the side of the syringe consisting of one letter and three numbers.

The letter is a lot number used for manufacturing purposes and the three numbers are the expiration date. The first two numbers are the month, and the third number is the last number of the year.



**For product MSDS, please visit our website:
www.ultradent.com**

For professional use only.

U.S. federal law restricts the sale of this device by or on the order of a dentist.

Keep out of reach of children.

For immediate reorder and/or complete descriptions of Ultradent's product line, refer to Ultradent's catalog or call Toll Free **1-800-552-5512**.

Outside U.S. call (801) 572-4200

or visit www.ultradent.com.

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ULTRADENT
PRODUCTS, INC.

Manufactured by Ultradent Products, Inc.
505 West 10200 South,
South Jordan, Utah 84095, USA Made in the USA

#10115.4 021011

PRINCIPAL DISPLAY PANEL - 1.2ml Syringe Label

Flor-Opal®

REF/UP 224

• 20 - 1.2ml Flor-Opal
Sustained Release Fluoride Gel/

#22505.2

042208

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Flor-Opal®

REF/UP 224

• 20 - 1.2ml Flor-Opal

Sustained Release Fluoride Gel/
 DE-Fluorid-Gel mit langanhaltender Wirkung/
 FR-Gel de fluor à libération prolongée/
 NL-fluoridegel met aanhoudende werking/
 IT-Gel di fluoro a rilascio sostenuto/
 ES-Gel de Liberación Sostenida, con fluoruro/
 PT-Gel de flúor de Libertação Gradual/
 SV-Långsamt frisläppande fluorgel/
 DA-Fluorgel med forlænget frigivelse/
 FI-Pitkävaiikutteinen, fluorivaapauttava geeli/
 EL-Σταδιακής Απελευθέρωσης Φθοριούχο Ζελέ

#22505.2 042208



FLOR-OPAL SUSTAINED-RELEASE FLUORIDE

sodium fluoride gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51206-401
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Polyethylene Glycol 300 (UNII: 5655G9Y8AQ)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51206-401-01	20 in 1 PACKAGE		

1	1.2 mL in 1 SYRINGE, PLASTIC; Type 0: Not a Combination Product		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/31/1990	

Labeler - Ultradent Products, Inc (013369916)

Establishment

Name	Address	ID/FEI	Business Operations
Ultradent Products, Inc		013369916	MANUFACTURE(51206-401)

Revised: 12/2014

Ultradent Products, Inc