

**PHOCAL APF- sodium fluoride, hydrofluoric acid disc  
U.S.I.A. 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](#).*

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**phocal™**

easy interproximal therapy

**INSTRUCTIONS FOR USE**

**Purpose and Indications**

- **Phocal** disks are topical delivery vehicles designed to fluoridate interproximal tooth surfaces. This action aids in the prevention of dental caries on intact surfaces, arrests progress on surfaces with incipient carious lesions and enhances remineralization. **Phocal** disks are also effective at tooth restoration margins and furcations.
- **Phocal** disks are to be applied only by dental professionals at selected sites to achieve the desired benefits.

**Description**

- The patented **Phocal** topical fluoride disks are provided in two forms:
  - pink acidulated phosphate fluoride Apf disks
  - yellow non-acidic sodium fluoride pHn disks
- These thin, round disks contain 1.23% fluoride ions. Once positioned interproximally they rapidly expand, soften into a gel and release fluoride for approximately 10 minutes before biodegrading. This release period can be increased as explained in the Directions for Use.
- Each **Phocal Apf** disk contains 0.103mg of sodium fluoride and 0.009mg of hydrogen fluoride in a matrix of FD&C red 3, gum arabic, gelatin (of marine origin), propolis wax, phosphoric acid, sodium benzoate and water. These disks induce an optimized low pH environment that cleans and etches tooth surfaces and facilitates fluoride penetration and stimulates remineralization.
- Each **Phocal pHn** disk contains 0.122mg of sodium fluoride in a matrix of gum arabic, gelatin (of marine origin), propolis wax, sodium benzoate and water. These disks are less acidic than the **Phocal Apf** disks and will not etch ceramic crowns or tooth-colored restorations while inducing fluoridation and remineralization.

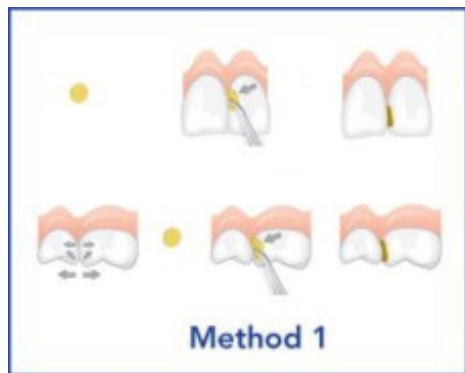
**Directions for Use**

- There are different methods for the placement of **Phocal** fluoride disks.
- The choice of placement method and **Phocal** type is subject to the discretion of the dental professional and is usually dependent upon the nature of the site being treated, interproximal tightness and the strength and type of adjacent restorations and teeth.
- Prior to treatment using either of the placement methods below, all debris and calculus should be removed from the selected site(s) and the site(s) should remain dry during placement. Premature wetting softens the disks and can compromise correct interproximal placement.

**Method 1 – Insertion of flat Phocal disks**

Recommended for anterior teeth and where spacing allows.

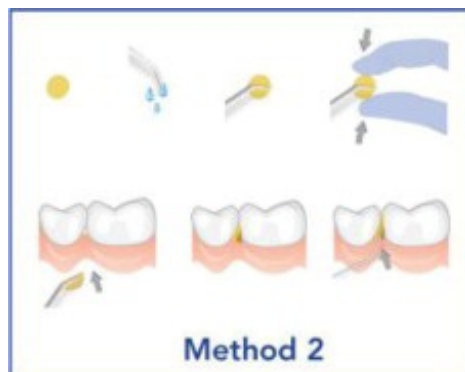
- When spacing allows, insert the flat **Phocal** disk interproximally with forceps and/or by hand directly between the contact points of the two adjacent teeth.
- In some cases, separation with wedges may be necessary prior to insertion.



### Method 2 – Insertion of folded Phocal disks

Recommended for posterior teeth and where spacing is restrictive.

- Where spacing is restricted, or where the apical regions such as tooth restoration margins must be reached, the disk can be folded into a V shape and easily inserted below the contact point.
- To fold the **Phocal** disk, lightly dampen the tips of a pair of thin forceps and shake off excess water, while keeping your hands completely dry. Use the tip of the thin forceps to moisten only the midline of the disk by moving the forceps tip back and forth along the midline. Be sure that midline is damp enough so the disk can fold without snapping.
- Then hold the disk at the midline with the thin forceps and gently fold the disk into a V shape with dry fingers. If you feel that the disk could snap, stop folding and repeat the midline moistening step.
- Insert the folded **Phocal** disk by hand and/or with forceps interproximally, with the apex at or below the contact area but over the gingival papillae and with each folded flap in contact with the wall of the adjacent teeth.
- The folded **Phocal** disk apex can be pushed further into the contact area. To accomplish this, insert a thin probe under the fold of the disk to apply coronal pressure alone, or simultaneously with an apical wedge force from the interproximal occlusal surface.



- In rare cases nickel titanium springs, elastic O-rings or Maxian strips can be used to separate teeth but this is usually a slower process which requires two visits: one for separation and then one for disk placement.
- To accelerate the initial reactions of **Phocal** disks a curing light can be applied for 3-10 seconds.

- To extend the fluoride release time period, a varnish can be applied to partially cover the interproximal site or disk occlusally, buccally or/and lingually. However the disk should not be completely coated with varnish.
- To shorten the release time the disks can be removed using an appropriate instrument, dental floss and/or aspiration.
- If **Phocal Apf** is used, in order to guard against possible etching of porcelain crowns or tooth-colored restorations, a protective matrix should be used. With **Phocal pHn** there is no risk of etching.
- Advise the patient not to eat, drink or rinse for at least 30 minutes after treatment.
- If multiple applications are necessary, treat no more than 8 sites at a time and delay subsequent **Phocal** applications for at least a day.
- If deemed necessary, patients may be recalled at intervals of 2 to 12 months for repeated treatments.
- **Phocal** disks are versatile, and with specific gentle moisturization they can be trimmed, rolled, or folded to fit other inaccessible areas such as furcations.

### **Warnings**

- In rare cases, sensitivity or adverse reactions may be experienced. In such cases immediately remove the disks while preventing swallowing and refer the patient to a physician.
- Patients less than 12 years old and patients with special needs should remain under professional supervision until the **Phocal** disks have biodegraded or have been removed.
- The disks are not intended for systemic ingestion and should be kept out of children's reach. If more than 20 disks are accidentally swallowed, seek immediate medical assistance.
- **Phocal** should not be applied in sites with: gingival inflammation, immediately prior to or after oral soft tissue surgery and in cases of known allergies to any of the **Phocal** ingredients.
- **Phocal** is to be sold as unbroken boxes with all disks sealed within the blister packs and is to be used for application in the dental office by professionals only.
- When **Phocal** treatment is utilized, routine systemic and topical administrations of fluoride should be suspended during the day of application.
- Since the propolis wax and gelatin used in Phocal disks are natural products, they may occasionally interact to produce brownish spots or discoloration. This does not indicate that there is any hazard or danger in using the product.
- Recommended storage temperatures are 40°F-75°F (5°C-25°C).

### **Responsibility of the Professional**

- **Phocal** disks have been developed for use only by licensed professionals in the dental care setting. Colldent Ltd warrants the quality of the products for the uses described and when used in the manners outlined here and in our sales and delivery documents. It is the responsibility of the professional to use the products in such manner.

### **For additional information**

**www.Phocaltherapy.com • 888-Phocal-3 (746-2253)**

### **QUICK REFERENCE INSERTION GUIDE**

**The interproximal sites and disk must be kept dry during placement.**

**Method 1 – Insertion of flat Phocal disks**

**Recommended for anterior teeth and where spacing allows**



When spacing allows, insert the disk with forceps and/or by hand.



In some cases, separation with wedges may be necessary prior to insertion.

### Method 2 – Insertion of folded Phocal disks

**Recommended for posterior teeth and where spacing is restrictive**

When spacing is restrictive, the disk can be folded and easily inserted below the contact point.



To fold, lightly dampen the tips of a pair of **thin** forceps and shake off excess water, while keeping your hands completely dry.

Use the tip of the thin forceps to moisten **only** the midline of the disk by moving the forceps tip back and forth along the midline. Then hold the disk along the midline with the thin forceps and gently fold the disk into a V shape with dry fingers.

If you feel that the disk could snap, stop folding and repeat the midline moistening step.



Insert the folded disk below the contact area as shown.

Use a thin probe to push the disk further into the contact area.

Principal Display panel – Box Label

fluoride treatment disks

for professional use only

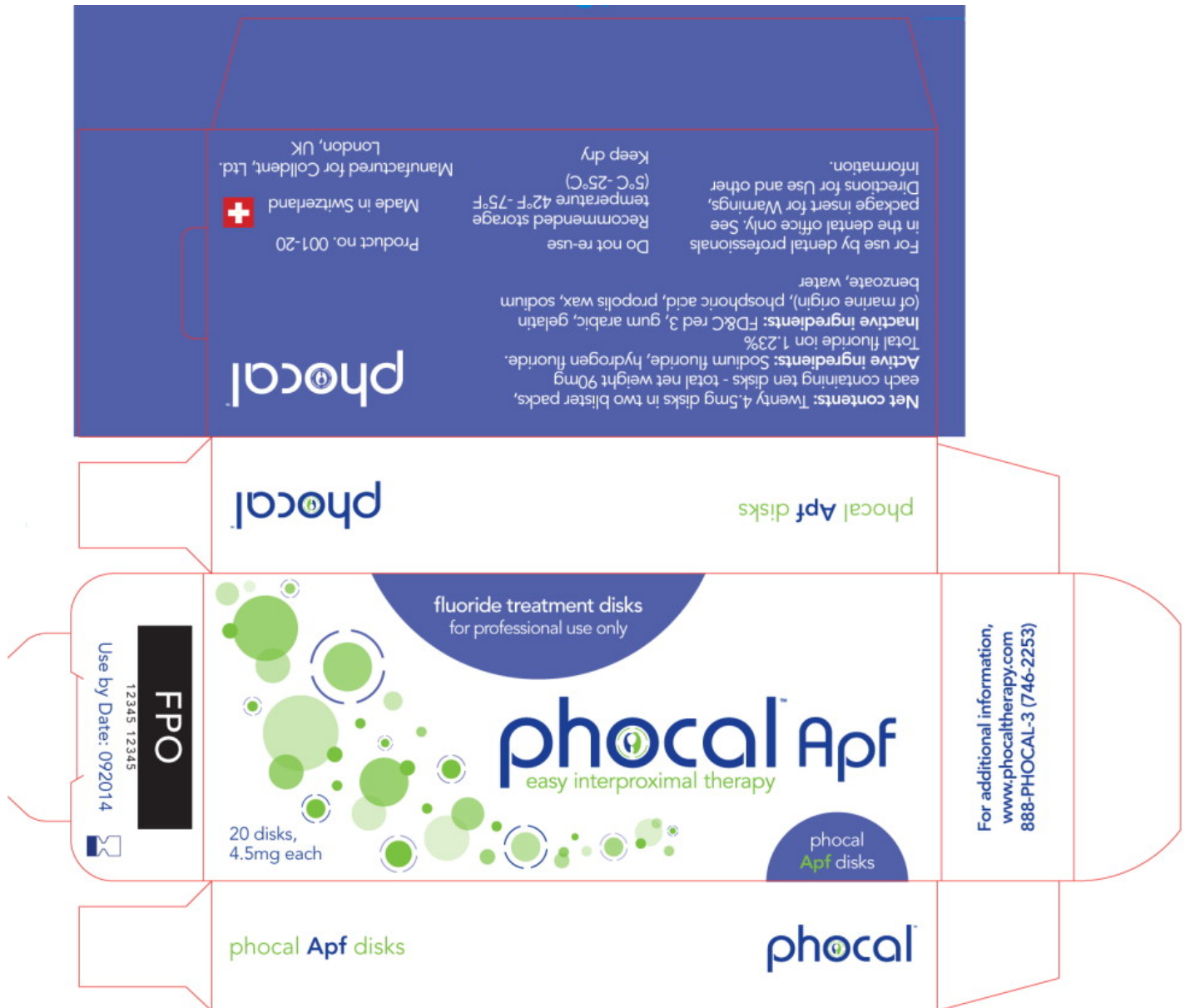
phocal™ Apf

easy interproximal therapy

20 disks,  
4.5mg each

phocal

Apf disks



## PHOCAL APF

sodium fluoride, hydrofluoric acid disc

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:559 18-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Sodium Fluoride</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0466 mg
<b>HYDROFLUORIC ACID</b> (UNII: RGL5YE86CZ) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0094 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>FD&amp;C Red No. 3</b> (UNII: PN2ZH5LOQY)	
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>gelatin</b> (UNII: 2G86QN327L)	
<b>PROPOLIS WAX</b> (UNII: 6Y8XYV2NOF)	
<b>phosphoric acid</b> (UNII: E4GA8884NN)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>water</b> (UNII: 059QF0K00R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:55918-001-20	2 in 1 BOX		
1		10 in 1 BLISTER PACK		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		01/01/2013	

**Labeler** - U.S.I.A. Inc (078525286)

Revised: 2/2013

U.S.I.A. Inc