

## Prescribing Information

### ControlRx™ 1.1% Sodium Fluoride Dentifrice

**DESCRIPTION:** ControlRx dentifrice is a prescription formulation for use in the prevention of dental caries. This formulation contains 1.1% sodium fluoride in a neutral pH base and a mild abrasive to help remove dental plaque, debris and stain.

**ACTIVE INGREDIENTS:** Sodium Fluoride 1.1% w/w.

**INACTIVE INGREDIENTS:** Water, Sorbitol, Hydrated Silica, Glycerin, MICRODENT® 2.0% w/v - a patented ULTRAMULSION® of Dimethicone and Poloxamer 407, PEG 12, Flavor, Cellulose Gum, Sodium Lauryl Sulfate, Titanium Dioxide, Sodium Saccharin.

**CLINICAL PHARMACOLOGY:** The use of higher-concentration fluoride products results in greater reductions in the incidence of dental caries. ControlRx dentifrice provides enhanced remineralization of demineralized enamel and enhanced protection against subsequent acid challenges, relative to over the counter fluoride products.

**INDICATIONS AND USAGE:** ControlRx dentifrice is indicated for use as part of a professional program for the prevention and control of dental caries. ControlRx dentifrice is applied to the teeth using a toothbrush. ControlRx dentifrice should be used once daily in place of a conventional toothpaste, unless otherwise instructed by a dental professional.

**CONTRAINDICATIONS:** Do not use in children less than 6 years of age unless recommended by a dental professional.

**WARNINGS:** Do not swallow. Keep out of reach of children. Frequent ingestion may result in dental fluorosis in children less than 6 years of age, especially if community water fluoridation exceeds 0.6 ppm fluoride ion. Use in children less than 6 years of age requires special supervision to prevent swallowing. Carefully read all instructions before using this product.

**ADVERSE REACTIONS:** Allergic reactions and other idiosyncrasies have been rarely reported.

**OVERDOSAGE:** Medical attention should be sought if more than a thin ribbon or pea-sized amount is accidentally swallowed. A thin ribbon or pea-sized amount of ControlRx dentifrice weighs approximately 0.3g and contains approximately 1.5mg of fluoride ion. A 2 oz tube contains 282mg of fluoride ion.

**DOSAGE AND ADMINISTRATION:** Follow these instructions unless otherwise instructed by a dental professional. Use once daily. Apply a thin ribbon or pea-sized amount of ControlRx dentifrice to a soft-bristled toothbrush, and brush teeth for two minutes. After brushing, adults should expectorate. Children 6 to 16 years of age should expectorate and thoroughly rinse mouth with water.

**HOW SUPPLIED:** 2 oz (57g) net wt. of paste in laminate tubes.

Berry Flavor NDC 48878-3101-6, Refreshing Vanilla Mint Flavor NDC 48878-3100-6

**STORAGE:** Do not freeze or expose to extreme heat.

**Rx only.**

### ControlRx™ Multi 1.1% Sodium Fluoride Dentifrice

**DESCRIPTION:** ControlRx Multi dentifrice is a prescription formulation for use in the prevention of dental caries. This formulation contains 1.1% sodium fluoride in a neutral pH base and a mild abrasive to help remove dental plaque, debris and stain.

**ACTIVE INGREDIENTS:** Sodium Fluoride 1.1% w/w

**INACTIVE INGREDIENTS:** Purified Water, Xylitol, Hydrated Silica, Glycerin, Cellulose Gum, Flavor, Simethicone, Sodium Lauryl Sulfate, Sodium Saccharin.

**CLINICAL PHARMACOLOGY:** The use of higher-concentration fluoride products results in greater reductions in the incidence of dental caries. ControlRx Multi dentifrice provides enhanced remineralization of demineralized enamel and enhanced protection against subsequent acid challenges, relative to over the counter fluoride products.

**INDICATIONS AND USAGE:** ControlRx Multi dentifrice is indicated for use as part of a professional program for the prevention and control of dental caries. ControlRx Multi dentifrice is applied to the teeth using a toothbrush. ControlRx Multi dentifrice should be used once daily in place of a conventional toothpaste, unless otherwise instructed by a dental professional.

**CONTRAINDICATIONS:** Do not use in children less than 6 years of age unless recommended by a dental professional.

**WARNINGS:** Do not swallow. Keep out of reach of children. Frequent ingestion may result in dental fluorosis in children less than

## Ordering Information

### ControlRx™ *Multi* 1.1% Sodium Fluoride 5000 ppm F- Dentifrice Plus Xylitol

Item	Price (per tube)		
12105 - Vanilla-Mint - 2oz tube	24+ @ \$7.15	48+ @ \$6.80	144+ @ \$6.30

### ControlRx™ 1.1% Sodium Fluoride 5000 ppm F- Dentifrice

Item	Price (per tube)		
12102 - Vanilla-Mint - 2oz tube	24+ @ \$6.95	48+ @ \$6.30	144+ @ \$5.70
12100VT - Vanilla-Mint Twin Pack - Two 2oz tubes	24+ @ \$11.90	48+ @ \$10.90	144+ @ \$9.55
12100B - Berry - 2oz tube	24+ @ \$6.95	48+ @ \$6.30	144+ @ \$5.70

### ControlRx™ Gel 1.1% Sodium Fluoride 5000 ppm F- Gel

Item	Price (per tube)		
12103 - Vanilla-Mint - 2oz tube	24+ @ \$6.30	48+ @ \$5.70	144+ @ \$5.10

**3M ESPE**

OMNI Preventive Care  
1500 N. Florida Mango Road  
West Palm Beach, FL 33409  
1-800-445-3386

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 **OMNI**  
Preventive Care

New

# Great Protection.



# ControlRx™ *Multi*

## *1.1% Sodium Fluoride Dentifrice with Xylitol*

**3M ESPE**

# 5000 ppm Fluoride Protection Plus Xylitol...



# We've Got You Covered.

*Fluoride, at appropriate levels, has been proven to be beneficial throughout life. There are numerous risk factors that may require 5000 ppm fluoride therapy.*

- Exposed root surfaces
- Orthodontic appliances
- History of cavities
- Diets high in sugars and starches
- Xerostomia
- Crowns and/or bridges

ControlRx™ *Multi* 1.1% Sodium Fluoride Dentifrice, the newest member of the ControlRx brand of 5000 ppm fluoride products, also contains xylitol. This all natural ingredient stimulates saliva flow and is an excellent addition to this proven therapy. Whether a patient can benefit most from original ControlRx dentifrice with its lower abrasive formula, ControlRx Gel tray-based therapy or new ControlRx *Multi* dentifrice with xylitol is best determined by a dental professional. We just wanted to make sure you had the help you needed.

### ControlRx™ *Multi* 1.1% Sodium Fluoride 5000 ppm F- Dentifrice Plus Xylitol

- Contains xylitol
- Provides over 4 times more fluoride than regular toothpaste
- Refreshing Vanilla-Mint flavor

### ControlRx™ 1.1% Sodium Fluoride 5000 ppm F- Dentifrice

- Has a low abrasive formula that is ideal for patients with exposed dentin
- Provides over 4 times more fluoride than regular toothpaste
- Refreshing Vanilla-Mint and Berry flavors

### ControlRx™ Gel 1.1% Sodium Fluoride 5000 ppm F- Gel

- Provides protection from xerostomia-related caries for cancer patients undergoing radiation treatments
- Can be used as a tray-based application or as a brush-on treatment
- Refreshing Vanilla-Mint flavor

Coming Soon!



**ControlRx™ *Multi* 1.1% Sodium Fluoride 5000 ppm F- Dentifrice Plus Xylitol**



**ControlRx™ 1.1% Sodium Fluoride 5000 ppm F- Dentifrice**



**ControlRx™ 1.1% Sodium Fluoride 5000 ppm F- Gel**



**ControlRx™**  
***Multi***  
1.1% Sodium Fluoride  
Dentifrice with Xylitol

For more information or to set up a staff meeting, visit [www.3mespe.com/preventivecare.com](http://www.3mespe.com/preventivecare.com)