ORAL-B NEUTRACARE MINT - neutral sodium fluoride gel
Oral-B Laboratories

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.

Package.Label Principal Display Panel

NeutraCare
Home Topical Treatment (1.1% w/w Neutral Sodium Fluoride)

Active Ingredient: Sodium Fluoride 1.1% w/w (0.5% fluoride ion)

DESCRIPTION: Oral-B NeutraCare Home Topical Treatment is a mint flavored 1.1% w/w neutral sodium fluoride aqueous solution.

Inactive Ingredients: Purified water, Sorbitol, Carbopol, Sodium hydroxide, Mint flavor, Methylparaben, Sodium saccharin, Propylparaben.

CLINICAL PHARMACOLOGY: Topical sodium fluoride preparations alter the composition and crystalline structure of tooth enamel promoting remineralization, increasing the resistance of tooth enamel to acid dissolution.

INDICATION AND USE:A once daily topical neutral aqueous solution for the prevention of dental caries.

CONTRAINDICATIONS: • Do not use in patients with hypersensitivity to fluoride.
• Do not use in patients with dysphagia.

WARNINGS:
• **DO NOT SWALLOW**. An occasional accidental ingestion of a usual treatment dose (a thin ribbon) is harmless. If more than used for treatment is swallowed, administer calcium (e.g. milk) and get medical help or contact a Poison Control Center right away.
• **Keep out of the reach of infants and children under 12 years.**
• Children under 12 years should use this product only under adult supervision to prevent swallowing. Safety and effectiveness below age 6 have not been established.

PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility: No evidence of carcinogenicity was observed in female and male mice at doses ranging from 2.4 to 18.8 mg/kg sodium fluoride of body weight (3,4). Equivocal evidence of carcinogenicity was reported in male rats at doses ranging from 2.5 to 4.1 mg/kg fluoride, but no evidence of carcinogenicity was observed in female rats (3,4). In another study, no carcinogenicity was observed in rats treated with fluoride up to 25 mg/kg of body weight (5). Overall, epidemiological studies do not show an association between fluoridated drinking water and increased cancer risk in humans (7).
Fluoride ion is not mutagenic in standard bacterial systems but has been associated with genetic aberrations in cultured human cells at doses much higher than expected for human exposure (6,8). Some in vivo studies report chromosomal aberrations in rodents while other studies using similar protocols report negative results (7).
Potential adverse reproductive effects of fluoride exposure in humans have not been adequately evaluated. Adverse reproductive effects of fluoride have been reported in animal studies, but at high concentrations sufficient to produce other manifestations of toxicity (9).

Pregnancy:Teratogenic Effects: Pregnancy Category B. Fluoride readily crosses the placenta (7,9). Animal studies (rats and rabbits) have shown that fluoride
is not a teratogen (10,12,13). Maternal exposure to 18 mg Fluoride/kg of body weight did not affect maternal body weight, litter size or fetal weight and did not increase frequency of skeletal or visceral malformations (10). There are no adequate and well-controlled studies in pregnant women. Several

epidemiological studies show no increase in birth defects in areas with fluoridated water compared to areas with low fluoridated water (7). However, caution should be exercised when fluoride is administered to pregnant women.

Nursing mothers: Due to the relative insensitivity of human milk fluoride levels to changes in maternal fluoride intake, and due to the very low concentrations of fluoride in human milk, fluoride supplementation during lactation would not be expected to significantly affect fluoride intake by the nursing infant (11). However, caution should be exercised when fluoride is administered to nursing women.

Pediatric use: The use of fluoride solutions, gels, and foams containing up to 1.23 % fluoride ion as caries preventives in pediatric patients aged 6 to 16 years is supported by clinical studies in students aged 6 to 12 years (1,2). Safety and effectiveness in pediatric patients below the age of 6 years has not been established. Please refer to CONTRAINDICATIONS and WARNINGS sections.

Geriatric use: No overall differences in safety or effectiveness have been observed between geriatric and younger patients. This drug is known to be substantially excreted by the kidney, therefore the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS: Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache and weakness. In patients with mucositis, gingival tissues may be hypersensitive to the flavor.

OVERDOSAGE: Accidental ingestion of large amounts of fluoride can result in acute irritation of the mouth and gastrointestinal tract as well as the development of gastrointestinal symptoms such as nausea, vomiting, diarrhea, hematemesis epigastric cramping and abdominal pain. If large amounts of fluoride equal to or greater than 5 mg fluoride/kg body weight (2.3 mg fluoride/lb body weight) are ingested, give calcium (e.g. milk, 5% calcium gluconate or calcium lactate solution) orally to relieve gastrointestinal symptoms and admit immediately to a hospital facility. A treatment dose (approximately a gram) of NeutraCare contains approximately 5.1mg fluoride. One 2 FL OZ (60ml) tube contains approximately 336 mg fluoride.

DOSAGE AND ADMINISTRATION: Adults and Children 6 years and over:
• Use daily after normal brushing and flossing, preferably at bedtime.
• Apply a thin ribbon of treatment to teeth with a toothbrush and leave in place for one minute.
• Expectorate. DO NOT SWALLOW.
• Do not eat or drink for at least 30 minutes afterwards except children 6 to 18 years who should rinse mouth thoroughly after use.
Children under 12 years:
• Should use this product only under adult supervision to prevent swallowing.

HOW SUPPLIED: NeutraCare is available in a plastic tube containing 2 FL OZ (60ml) in mint flavor, NDC 0041-241-22.

REFERENCES:
(1.) Wellock, W.D. and Brudevold, F.: Arch. Oral Biol., 10, 453-460 (1965) (2.) Jiang, H et al.: J. Dent, 33, 469-473 (2005) (3.) National Toxicology Program: NTP TR 393, NIH Publication 91-2842, (1990) (4.) Bucker, J.R. et al.: Int. J. Cancer 48, 733-737 (1991) (5.) Maurer, J.K. et al.: J. Natl. Cancer Inst. 82, 1118-1126 (1990) (6) Martin, G.R. et al.: Mutat. Res. 66, 159-167 (1979) (7.) Agency for Toxic Substances and Disease Registry: Toxicological Profile for Fluoride (2003)
(8.) Aardema, M.J. et al.: Mutat. Res. 331 (1), 171-172 (9.) National Research Council: Fluoride in Drinking Water (2006) (10.) Heindel, J.J. et al.: Fundam Appl Toxicol, 30, 162-177 (1996) (11.) Institute of Medicine, Food and Nutrition Board: Dietary Reference Intakes (1997) (12.) Collins, T.F. et al.: Food Chem. Toxicol. 33 (11), 951-960 (13.) Collins, T.F. et al.: Food Chem Toxicol. 39 (8), 867-876

NeutraCare


NDC 0041-0241-22
NPN 02248311
Oral-B
NeutraCare®
Home Topical Treatment (1.1% w/w Neutral Sodium Fluoride)
Traitement topique pour usage à domicile (Fluorure de sodium neutre à 1,1 % p/p)
Rx only (in U.S.A)
Sur ordonnance seulement (in U.S.A)
MINT
MENTHE
60 mL / 2 FL OZ / 2 OZ LIQ.
Description:
Oral-B NeutraCare® Home Topical Treatment is a 1.1% w/w neutral sodium fluoride aqueous solution.
Active /Medicinal Ingredient:
Sodium Fluoride 1.1% w/w (0.5% fluoride ion or 5066 ppm fluoride ion).
Inactive/Non-medicinal Ingredients:
Purified water, Sorbitol, Carbopol, Sodium hydroxide, Mint flavor, Methylparaben, Sodium saccharin, Propylparaben.
Indications and Use:
A once daily topical neutral aqueous solution for the prevention of dental caries. This is not a dentifrice.
Warnings:
DO NOT SWALLOW.
Keep out of reach of children.
If more than used for treatment is swallowed, administer calcium (e.g. milk) and get medical help or contact a Poison Control Center right away. For professional use only.
Usage Instructions:
After brushing with dentifrice, apply a thin ribbon of the formulation to teeth for at least 1 minute using a toothbrush. Expectorate and do not eat, drink or rinse for at least 30 minutes.
Questions? 1-800-566-7252
www.dentalcare.com
DO NOT USE IF INNER FOIL IS TORN, CUT OR MISSING.
NE PAS UTILISER SI LE SCEAU DE PROTECTION INTÉRIEUR EST DÉCHIRÉ, ABÎMÉ OU MANQUANT.
SEE PRODUCT INFORMATION LEAFLET FOR COMPLETE DETAILS.
POUR PLUS DE DÉTAILS, CONSULTER LA NOTICE D'ACCOMPAGNEMENT DU PRODUIT.
Description :
Le traitement topique pour usage à domicile Oral-B NeutraCare® est une solution aqueuse de fluorure de sodium neutre à 1,1 % p/p.
Ingrédient actif / médicamenteux :
Fluorure de sodium à 1,1 % p/p (0,5 % d'ions de fluorure ou 5066 ppm d'ions de fluorure).
Ingrédients inactifs/non-médicamenteux :
Eau purifiée, sorbitol, carbopol, hydroxyde de sodium, arôme de menthe, méthylparabène, saccharinate de sodium, propylparaben.
Indications et mode d'emploi :
Appliquer une fois par jour la solution aqueuse neutre pour prévenir la carie dentaire. Ce produit n'est pas un dentifrice.
Mises en garde :
NE PAS AVALER.
Tenir hors de la portée des enfants. En cas d'ingestion d'une quantité supérieure à la quantité recommandée, donner du calcium (du lait, par exemple) et consulter sans délai un médecin ou un centre antipoison. Réservé à un usage professionnel.
Mode d'emploi :
Après s'être brossé les dents avec un dentifrice, appliquer un mince filet de produit sur les dents à l'aide de la brosse à dents et laisser agir durant une minute. Cracher. Ne pas boire ni manger ni se rincer la bouche durant au moins 30 minutes après avoir utilisé le produit.
U.S.A./É.-U : Manufactured for/Fabriqué pour Oral-B Laboratories, a Division of/une division de Procter & Gamble, Cincinnati, OH 45202
Canada : Distr. by/par : Oral-B Laboratories, a Division of/une division de Procter & Gamble Inc., Toronto, ON M5W 1C5
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ORAL-B NEUTRACARE MINT

neutral sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0041-0241
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride ion - UNII:Q80VPU408O)	Fluoride ion	11 mg in 1 g

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	SPEARMINT (Mint Flavor)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0041-0241-22	60 g in 1 CARTON		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
unapproved drug other		05/04/2000	

Labeler - Oral-B Laboratories (183102243)

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