

**CURAPROX BLACK IS WHITE- toothpaste, sodium monofluorophosphate paste, dentifrice**  
**Curaden AG**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Adults and children 2 years of age and older:

Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

Children under 6 years of age:

Instruct in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.

Consult dentist or doctor.

Aids in the prevention of dental cavities.

AQUA, SORBITOL, HYDRATED SILICA, GLYCERIN, CHARCOAL POWDER, AROMA, DECYL GLUCOSIDE, COCAMIDOPROPYL BETAINE, TOCOPHEROL, XANTHAN GUM, MALTODEXTRIN, MICA, HYDROXYAPATITE (NANO), POTASSIUM ACESULFAME, TITANIUM DIOXIDE, MICROCRYSTALLINE CELLULOSE, SODIUM CHLORIDE, POTASSIUM CHLORIDE, CITRUS LIMON PEEL OIL, SODIUM HYDROXIDE, ZEA MAYS STARCH, AMYLOGLUCOSIDASE, GLUCOSE OXIDASE, URTICA DIOICA LEAF EXTRACT, POTASSIUM THIOCYANATE, CETEARYL ALCOHOL, HYDROGENATED LECITHIN, MENTHYL LACTATE, METHYL DIISOPROPYL PROPIONAMIDE, ETHYL MENTHANE CARBOXAMIDE, STEARIC ACID, MANNITOL, SODIUM BISULFITE, TIN OXIDE, LACTOPEROXIDASE, LIMON

Sodium monofluorophosphate 0.723%  
(0.095% W/V fluoride ion)

Fluoride toothpaste

Children under 6 years of age:

Consult dentist or doctor

Keep out of reach of children under 6 years of age.

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

Keep out of reach of children under 6 years of age. If more than used for brushing is

accidentally swallowed, get medical help or contact a Poison Control Center right away.

Apply small bead on bristles of toothbrush. Use bristles with toothpaste to brush all around teeth to include gum line.

**Use**

Aid in the prevention of dental cavities.

**Use**

Aids in the prevention of cavities.

**Outer package artwork**

FLUORIDE  
WHITENING  
TOOTHPASTE



### Drug Facts

Active Ingredients	Purpose
Sodium monofluorophosphate 0.723% (0.095% W/W fluoride ion).....	Fluoride toothpaste

**Use**

■ Aids in the prevention of dental cavities.

**Warning**

**Keep out of reach of children under 6 years of age.** If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Adults and children 2 years of age and older	Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor
Children under 6 years of age	Instruct in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision
Children under 6 years of age	Consult dentist or doctor

# CURAPROX BLACK IS WHITE

+ ACTIVATED CARBON  
& HYDROXYAPATITE

FRESH LIME-MINT



## **Inactive ingredients**

AQUA, SORBITOL, HYDRATED SILICA, GLYCERIN, CHARCOAL POWDER, AROMA, DECYL GLUCOSIDE, COCAMIDOPROPYL BETAINE, TOCOPHEROL, XANTHAN GUM, MALTODEXTRIN, MICA, HYDROXYAPATITE (NANO), POTASSIUM ACESULFAME, TITANIUM DIOXIDE, MICROCRYSTALLINE CELLULOSE, SODIUM CHLORIDE, POTASSIUM CHLORIDE, CITRUS LIMON PEEL OIL, SODIUM HYDROXIDE, ZEAMAYS STARCH, AMYLOGUCOSIDASE, GLUCOSE OXIDASE, URTICA DIOICA LEAF EXTRACT, POTASSIUM THIOCYANATE, CETEARYL ALCOHOL, HYDROGENATED LECITHIN, MENTHYL LACTATE, METHYL DIISOPROPYL PROPIONAMIDE, ETHYL MENTHANE CARBOXAMIDE, STEARIC ACID, MANNITOL, SODIUM BISULFITE, TIN OXIDE, LACTOPEROXIDASE, LIMONENE



MADE IN SWITZERLAND

**curaden**  
ID better health for you



**ONLINE SHOP**  
[www.curaprox.com](http://www.curaprox.com)

## **CURADEN SWISS HEADQUARTERS:**

CURADEN AG, Amlehnstrasse 22, 6010 Kriens, CH - Switzerland

## **CURADEN LOCAL DISTRIBUTOR USA:**

Curaden USA, 4255 E McDowell Rd., #109, Mesa AZ 85215, USA

## **TO REPORT A SERIOUS ADVERSE EVENT CONTACT:**

Curaden USA, Inc., 4255 E McDowell Rd., #109, Mesa, AZ 85215, [support@curaproxusa.com](mailto:support@curaproxusa.com), Tel: 1-800-919-0120

Net Wt. 3 fl oz (90 mL)

**ONLINE SHOP**

www.curaprox.com

Art.-Nr. 73320680 | 1220-73314548 | 300101141/A



## CURAPROX BLACK IS WHITE

toothpaste, sodium monofluorophosphate paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71112-001
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.095 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>POTASSIUM THIOCYANATE</b> (UNII: TM7213864A)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71112-001-20	1 in 1 BOX	03/01/2021	
1		90 mL in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/01/2021	

**Labeler -** Curaden AG (481145555)

**Registrant -** Curaden AG (481145555)

## Establishment

Name	Address	ID/FEI	Business Operations
Trybol AG		480305077	manufacture(71112-001)

Revised: 7/2022

Curaden AG