

**DENBLAN WHITENING FORMULA ANTI CAVITY FLUORIDE- sodium monofluorophosphate paste, dentifrice
DARPHIN DIST.**

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.

**WHITENING FORMULA
DENBLAN
ANTICAVITY FLUORIDE TOOTHPASTE**

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76%

Purpose

Fluoride toothpaste

Use

Aids in the prevention of dental cavities.

Warnings

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.
- Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

Ingredients

water, dicalcium phosphate, calcium carbonate, silica, glycerin, sorbitol, algin, carica papaya (papaya) fruit extract, ananas sativus (pineapple) fruit extract, mentha viridis (spearmint) leaf oil, mentha arvensis leaf oil, usnea barbata (lichen) extract, angelica archangelica root oil, carum petroselinum (parsley) seed oil, foeniculum vulgare (fennel) oil, sodium lauryl sulfate, propylene glycol, sodium saccharin, limonene, sodium benzoate, sodium propylparaben, sodium methylparaben <ILN36886>.

DARPHIN

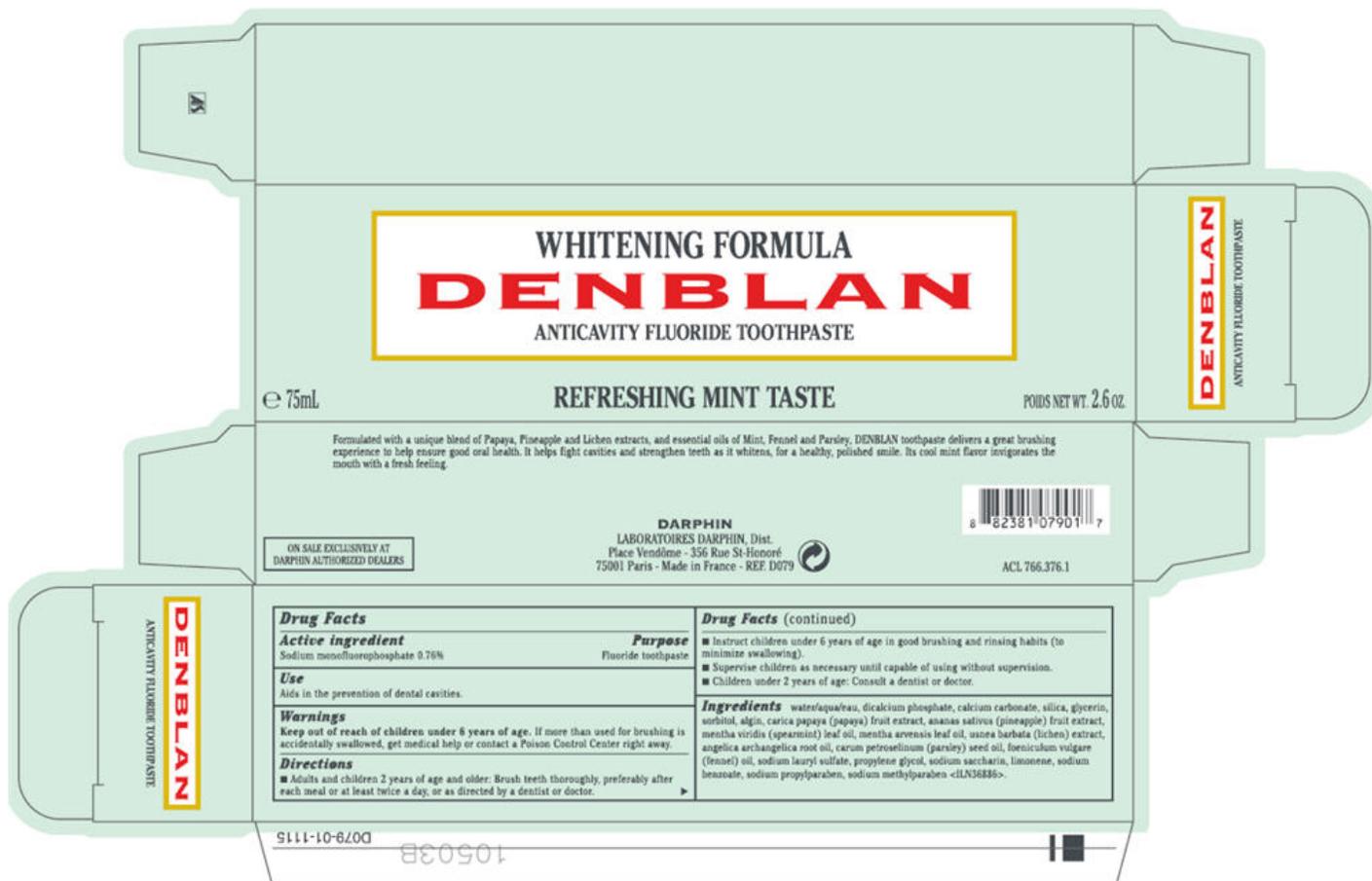
LABORATORIES DARPHIN, Dist.

PRINCIPAL DISPLAY PANEL - 75mL Carton

WHITENING FORMULA

DENBLAN
ANTICAVITY FLUORIDE TOOTHPASTE
REFRESHING MINT TASTE

e 75mL
 POIDS NET WT. 2.6 OZ.



DENBLAN WHITENING FORMULA ANTI CAVITY FLUORIDE

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16555-996
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	0.76 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
GLYCERIN (UNII: PDC6A3C0OX)
SORBITOL (UNII: 506T60A25R)
PAPAYA (UNII: KU94FIY6JB)
PINEAPPLE (UNII: 2A88ZO081O)
SPEARMINT OIL (UNII: C3M81465G5)
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)
USNEA BARBATA (UNII: D6DVA9TCAP)
ANGELICA ROOT OIL (UNII: B25G881UOX)
PARSLEY SEED OIL (UNII: XB8Q500O0Z)
FENNEL OIL (UNII: 59AAO5F6HT)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)
SODIUM BENZOATE (UNII: OJ245FE5EU)
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16555-996-01	1 in 1 CARTON		
1		75 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	08/01/2004	

Labeler - DARPHIN DIST. (105157494)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC Kabushiki Kaisha		712808195	RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE, RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
ARAMIS, INC		042918826	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		787336577	MANUFACTURE, RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		949264774	MANUFACTURE, RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		618107429	MANUFACTURE, RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
CCI Productions Parfums & Cosmetiques		268298408	MANUFACTURE

