

# TRUWELL DENTIWASH- sodium fluoride liquid ECOWORLDPHARM CO.,LTD

## Drug Facts

sodium fluoride

purified water, glycerin, xylitol, green tea extract, acetic acid, strawberry flavoring, sodium acetate, grapefruit seed extract, sodium benzoate, L-menthol, sodium saccharin, chitosan

aids in the prevention of dental cavities

KEEP OUT OF REACH OF THE CHILDREN

Adults and children 6 years of age and older:

use twice a day after brushing your teeth with a toothpaste

vigorously swish contents of one (1) 11mL packet between your teeth for 1 minute and then spit out

do not swallow the rinse

do not eat or drink for 30 minutes after rinsing

instruct children under 12 years of age in good rinsing habits (to minimize swallowing)

supervise children as necessary until capable of using without supervision

Children under 6 years of age: consult a dentist or doctor

if more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away

for dental use only



## TRUWELL DENTIWASH

sodium fluoride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61284-0013
Route of Administration	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.05 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>MALIC ACID</b> (UNII: 817L1N4CKP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61284-0013-2	250 in 1 PACKAGE	10/05/2023	
1	NDC:61284-0013-1	11 mL in 1 PACKAGE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	10/05/2023	

**Labeler** - ECOWORLDPHARM CO.,LTD (688735061)**Registrant** - ECOWORLDPHARM CO.,LTD (688735061)**Establishment**

Name	Address	ID/FEI	Business Operations
ECOWORLDPHARM CO.,LTD		688735061	manufacture(61284-0013)

Revised: 10/2023

ECOWORLDPHARM CO.,LTD