

# 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

Drug Facts	
<b>Active Ingredients</b> Sodium fluoride 0.05%	<b>Purpose</b> Anticavity
<b>Use</b> ■ aids in the prevention of dental cavities	
<b>Warnings</b> Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> 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	
<b>Other Information</b> Store at room temperature. Cold temperature may temporarily cloud product.	
<b>Inactive Ingredients</b> purified water, glycerin, malic acid, sodium citrate, chitosan, citric acid, citrus flavoring, xylitol, sodium benzoate, green tea extract, lemon flavoring, caramel color, L-menthol, sodium saccharin, propolis extract	

MADE IN KOREA

Bot. by Kowon&G Corp, 7006 Little River Topi, Ste. II, Ansan-si 4132002

IMPORTANT: Read directions for proper use.

30x11mL packets

**TRUWELL DENTIWASH**

sodium fluoride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61284-0012
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:61284-0012-2	30 in 1 PACKAGE	10/05/2023	
1	NDC:61284-0012-1	11 mL in 1 PACKAGE; Type 0: Not a Combination Product		

### Marketing Information

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

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

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

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ECOWORLDPHARM CO.,LTD		688735061	manufacture(61284-0012)