

**TIDALOVE SMILE MORE ORAL CARE- sodium fluoride tablet tablet
Paranmare**

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.

Active Ingredients(in each tablet) purpose

Sodium fluoride 1.54mg (0.7mg fluoride ion) anticavity

Inactive Ingredients

silicon dioxide, tetrasodium pyrophosphate, pyridoxine hydrochloride(vitamin B6), D-sorbitol, microcrystalline cellulose, xylitol, enzymatically modified stevia, bamboo salt, hydroxypropylcellulose, xanthan gum, sodium cocoyl glutamate, sodium bicarbonate, magnesium stearate, hydroxyapatite, tocopherol acetate(vitamin E), sodium ascorbate (vitamin C), L-menthol, combined flavor, green tea extract, eucalyptus oil, rosemary extract

Aids in the prevention of dental cavities

- Adults and children 6 years of age and older: Chew 1 tablet until crushed.
- Brush teeth thoroughly at least twice a day, or use as directed by a dentist or physician.
- Spit out: Do not swallow the tablet.
- Children under 6 years of age should be supervised when using this product.

Keep out of the reach of children.

Brush teeth thoroughly at least twice a day, or use as directed by a dentist or physician.

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

Do not use it for anything other than brushing teeth, and be careful not to swallow it. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.Keep out of the reach of children.

Small tablets may be a choking hazard for children under 3 years old.

Keep it away from the pets.

When using this product, if irritation or sensitivity occurs, discontinue use.

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Store at 25-30 °C (68-77°F). Protect from excessive moisture.

Gently chew 1 tablet until it crushed. Brush teeth thoroughly,

Adults and children 6 years of age and older: Chew 1 tablet until crushed.

Brush teeth thoroughly at least twice a day, or use as directed by a dentist or physician.

Spit out: Do not swallow the tablet.

Children under 6 years of age should be supervised when using this product.

| Drug Facts | |
|---|----------------|
| Active ingredient (in each tablet) | Purpose |
| Sodium Fluoride 1.54mg (0.7mg fluoride ion)..... | Anti-cavity |
| Uses | |
| ■ Aids in the prevention of dental cavities | |
| Warnings | |
| ■ Do not use it for anything other than brushing teeth, and be careful not to swallow it. | |
| ■ If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately. | |
| ■ Keep out of the reach of children. | |
| ■ Small tablets may be a choking hazard for children under 3 years old. | |
| ■ Keep it away from the pets. | |
| ■ When using this product, if irritation or sensitivity occurs, discontinue use. | |
| Directions | |
| ■ Adults and children 6 years of age and older: Chew 1 tablet until crushed. | |
| ■ Brush teeth thoroughly at least twice a day, or use as directed by a dentist or physician. | |
| ■ Spit out: Do not swallow the tablet. | |
| ■ Children under 6 years of age should be supervised when using this product. | |
| Other information | |
| Store at 25-30 °C (68-77°F). | |
| Protect from excessive moisture. | |
| Inactive Ingredients | |
| silicon dioxide, tetrasodium pyrophosphate, pyridoxine hydrochloride (vitamin B ₆), D-sorbitol, microcrystalline cellulose, xylitol, enzymatically modified stevia, bamboo salt, hydroxypropylcellulose, xanthan gum, sodium cocoyl glutamate, sodium bicarbonate, magnesium stearate, tocopherol acetate(vitamin E), sodium ascorbate(vitamin C), L-menthol, combined flavor, green tea extract, eucalyptus oil, grape seed extract, apple extract | |

Cinnamon

| Drug Facts | |
|---|----------------|
| Active ingredient (in each tablet) | Purpose |
| Sodium Fluoride 1.54mg (0.7mg fluoride ion) | Anti-cavity |
| Uses | |
| <ul style="list-style-type: none"> ■ Aids in the prevention of dental cavities | |
| Warnings | |
| <ul style="list-style-type: none"> ■ Do not use it for anything other than brushing teeth, and be careful not to swallow it. ■ If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center immediately. ■ Keep out of the reach of children. ■ Small tablets may be a choking hazard for children under 3 years old. ■ Keep it away from the pets. ■ When using this product, if irritation or sensitivity occurs, discontinue use. | |
| Directions | |
| <ul style="list-style-type: none"> ■ Adults and children 6 years of age and older: Chew 1 tablet until crushed. ■ Brush teeth thoroughly at least twice a day, or use as directed by a dentist or physician. ■ Spit out: Do not swallow the tablet. ■ Children under 6 years of age should be supervised when using this product. | |
| Other information | |
| Store at 25-30 °C (68-77°F). | |
| Protect from excessive moisture. | |
| Inactive Ingredients | |
| silicon dioxide, tetrasodium pyrophosphate, pyridoxine hydrochloride(vitamin B ₆), D-sorbitol, microcrystalline cellulose, xylitol, enzymatically modified stevia, bamboo salt, hydroxypropylcellulose, xanthan gum, sodium cocoyl glutamate, sodium bicarbonate, magnesium stearate, hydroxyapatite, tocopherol acetate(vitamin E), sodium ascorbate (vitamin C), L-menthol, combined flavor, green tea extract, eucalyptus oil, rosemary extract | |

Minty Yuzu

sodium fluoride tablet tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82756-001 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|----------------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | SODIUM FLUORIDE | 0.7 mg in 1.54 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) | |
| SORBITOL (UNII: 506T60A25R) | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SODIUM PYROPHOSPHATE (UNII: O352864B8Z) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| ROSEMARY (UNII: IJ67X351P9) | |
| SEA SALT (UNII: 87GE52P74G) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |
| SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| SODIUM ASCORBATE (UNII: S033EH8359) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | CITRUS | Imprint Code | none |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:82756-001-11 | 1.54 mg in 1 BAG; Type 0: Not a Combination Product | 06/10/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355 | 06/01/2022 | |

TIDALOVE SMILE MORE ORAL CARE

sodium fluoride tablet tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82756-002 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 0.7 mg in 1.54 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| SODIUM ASCORBATE (UNII: S033EH8359) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SODIUM PYROPHOSPHATE (UNII: O352864B8Z) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG) | |
| SORBITOL (UNII: 506T60A25R) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| SEA SALT (UNII: 87GE52P74G) | |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH) | |
| EUCALYPTUS OIL (UNII: 2R04ONI662) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |

Product Characteristics

| | | | |
|--------|----------|--------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | CINNAMON | Imprint Code | none |

Contains**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:82756-002-11 | 1.54 mg in 1 BAG; Type 0: Not a Combination Product | 06/10/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355 | 06/01/2022 | |

Labeler - Paranmare (049281321)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|---------------------------------|---------|-----------|-----------------------------------|
| SUNGWON PHARMACEUTICAL CO., LTD | | 689787898 | manufacture(82756-001, 82756-002) |

Revised: 12/2022

Paranmare