

AQUAPICK WHITENING BUBBLEPICK - sodium fluoride liquid

Aquapick Co., Ltd

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.

Drug Facts

sodium fluoride

allantoin, xylitol, greentea extract, sage extract, chamomile extract, grapefruit seed extract

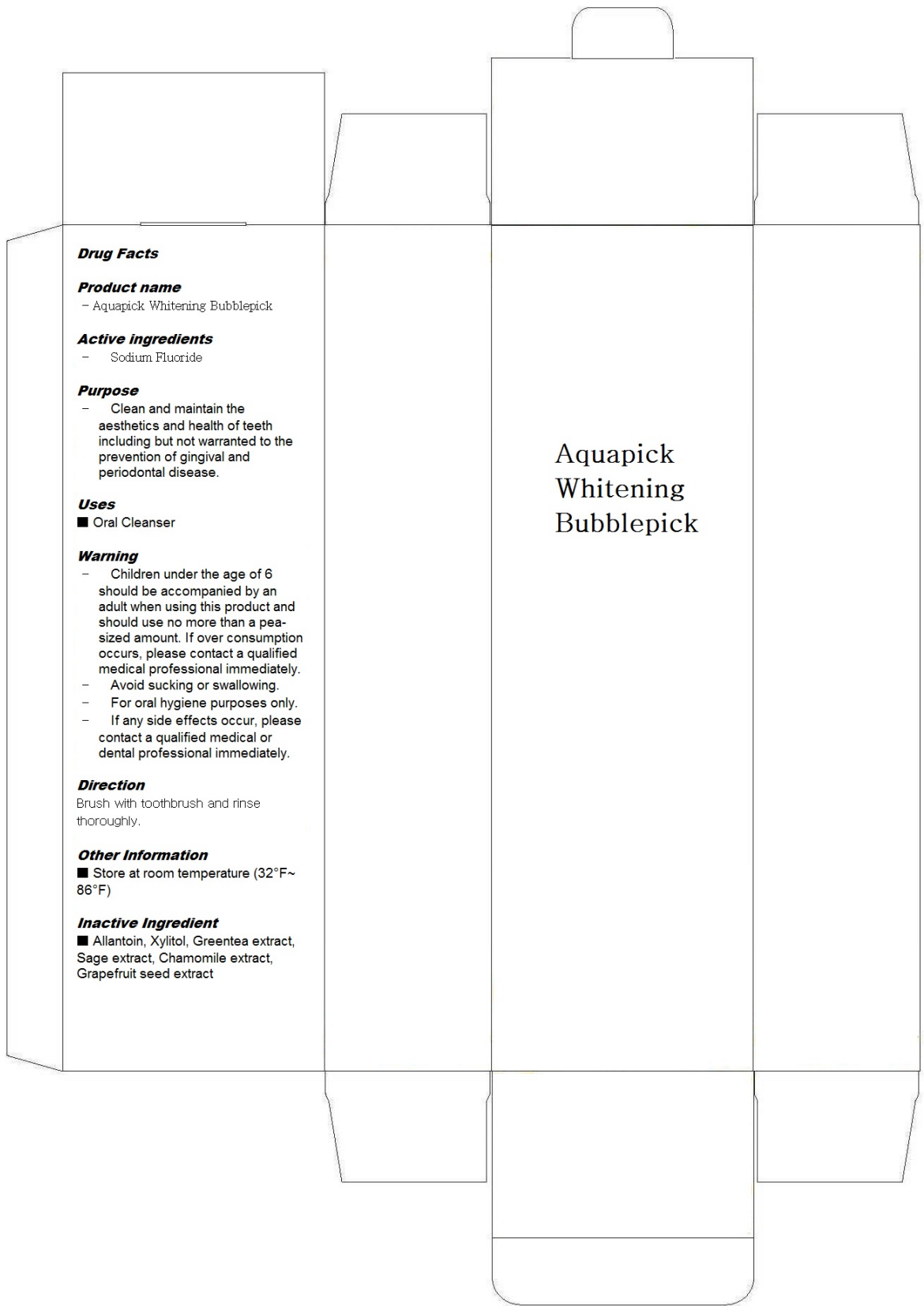
Clean and maintain the aesthetics and health of teeth including but not warranted to the prevention of gingival and periodontal disease

keep out of reach of the children

brush with toothbrush and rinse thoroughly

- Children under the age of 6 should be accompanied by an adult when using this product and should use no more than a pea-sized amount. If over consumption occurs, please contact a qualified medical professional immediately.
- Avoid sucking or swallowing.
- For oral hygiene purposes only.
- If any side effects occur, please contact a qualified medical or dental professional immediately.

for dental use only



Drug Facts

Product name

- Aquapick Whitening Bubblepick

Active ingredients

- Sodium Fluoride

Purpose

- Clean and maintain the aesthetics and health of teeth including but not warranted to the prevention of gingival and periodontal disease.

Uses

■ Oral Cleanser

Warning

- Children under the age of 6 should be accompanied by an adult when using this product and should use no more than a pea-sized amount. If over consumption occurs, please contact a qualified medical professional immediately.
- Avoid sucking or swallowing.
- For oral hygiene purposes only.
- If any side effects occur, please contact a qualified medical or dental professional immediately.

Direction

Brush with toothbrush and rinse thoroughly.

Other Information

■ Store at room temperature (32°F~86°F)

Inactive Ingredient

■ Allantoin, Xylitol, Greentea extract, Sage extract, Chamomile extract, Grapefruit seed extract

Aquapick
Whitening
Bubblepick

AQUAPICK WHITENING BUBBLEPICK

sodium fluoride liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58399-1001 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 0.001 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------------|----------|
| ALLANTOIN (UNII: 344S277G0Z) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| SAGE (UNII: 065C5D077J) | |
| CHAMOMILE (UNII: FGL3685T2X) | |
| GRAPEFRUIT (UNII: O82C39RR8C) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|----------------------|--------------------|
| 1 | NDC:58399-1001-1 | 50 mL in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355 | 05/02/2013 | |

Labeler - Aquapick Co., Ltd (688444236)

Registrant - Aquapick Co., Ltd (688444236)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|-------------------------|
| Kolmar Korea Co. Ltd | | 687846360 | manufacture(58399-1001) |