



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	91663	White Lightening
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Professional Dentist Supplies Pty Ltd	
<b>Postal Address</b>	3/8 Nicole Close, BAYSWATER NORTH, VIC, 3153 Australia	
<b>ARTG Start Date</b>	5/11/2002	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

The listing of this medicine is subject to statutory conditions of listing and additional conditions of listing imposed by the Secretary under the provisions of subsection 28(3) of the Therapeutic Goods Act 1989 by notice in writing.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

### Products

#### 1 . White Lightening

<b>Product Type</b>	Medicine Kit	<b>Effective Date</b>	12/11/2019 3:02:17 PM
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#### Permitted Indications

No Permitted Indications included on Record

#### Indication Requirements

No Indication Requirements included on Record

#### Standard Indications

No Standard Indications included on Record

#### Indications

For the bleaching, lightening and whitening of teeth. Stain removal / Helps remove stains from teeth. Chlorofluor Gel has a desensitising effect upon teeth that will enable bleaching to continue after a single two hour application. Chlorofluor Gel combines Chlorhexidine with Fluoride to improve gingival health and caries resistance.

#### Warnings

No Warnings included on Record

#### Additional Product information

#### Container information

<b>Type</b>	<b>Material</b>	<b>Life Time</b>	<b>Temperature</b>	<b>Closure</b>	<b>Conditions</b>
Bottle	Not recorded	3 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
1 x 30mL Aust L 21505	Not scheduled. Not considered by committee

#### Components

##### 1 . WHITE LIGHTENING (ARTG: 21505)

##### Active Ingredients

chlorhexidine gluconate	20 mg/mL
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sodium fluoride

15 microgram/mL

**Other Ingredients (Excipients)**

Anise Oil

carmoisine

Cinnamon Bark Oil

Clove Bud Oil

ethanol

menthol

monobasic ammonium phosphate

Peppermint Oil

polysorbate 20

polysorbate 80

potable water

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