



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	161119	Colgate Orthodontic Care Pack
ARTG entry for	Medicine Listed	
Sponsor	Colgate-Palmolive Pty Ltd	
Postal Address	GPO Box 3964, SYDNEY, NSW, 2001 Australia	
ARTG Start Date	16/04/2009	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Colgate Orthodontic Care Pack

Product Type	Medicine Kit	Effective Date	16/04/2009
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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

Maintaining good oral hygiene during orthodontic care.

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

- 1 . NEUTRAFLUOR 900 WEEKLY FLUORIDE RINSE sodium fluoride 0.2% w/v mouthwash bottle (ARTG: 67258)
- 2 . COLGATE TOTAL toothpaste tube (ARTG: 154432)
- 3 . Plaque Disclosing tablets (ARTG:)
- 4 . Interdental brushes (ARTG:)
- 5 . Orthodontic Toothbrush (ARTG:)



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