

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fluorigard Daily Rinse 0.05 % w/w Dental Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient

Sodium Fluoride Ph Eur 0.05% w/w (225 ppm F)

Excipient(s) with known effect:

The Flavour contains Allergens - Benzyl alcohol, Eugenol, Limonene, Linalool, and Geraniol.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Dental Solution

Clear blue minty liquid

4 CLINICAL PARTICULARS

4.1. Therapeutic Indications

To aid in protection against dental caries.

4.2. Posology and Method of Administration

For use by persons aged 6 years and over only

Not to be swallowed

Instructions for use:

- Use once per day, preferably after brushing teeth.
- Rinse 5-10ml around and between teeth for one minute and then spit out.
- Do not eat, drink or rinse mouth for at least fifteen minutes afterwards.

Method of administration: For oral use

4.3. Contra-Indications

Do not use this product if you are hypersensitive (allergic) to the active substance or to any of the excipients

4.4 Special warnings and precautions for use

Fluorigard Daily is not intended for use in children under the age of 6, see 4.2

Excess Dosage may cause nausea, and in children under seven, dental fluorosis.

Benzyl alcohol may cause mild local irritation. Propylene glycol may cause skin irritation.

This medicine contains a flavouring with benzyl alcohol, eugenol, limonene, linalool, and geraniol which may cause allergic reactions.

4.5. Interaction with other Medicinal Products and other Forms of Interaction

None known.

4.6. Pregnancy and Lactation

None stated.

4.7. Effects on Ability to Drive and Use Machines

Not relevant

4.8 Undesirable effects

None.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Caries prophylactic agents
ATC code: A01AA01

Sodium fluoride acts systemically (before tooth eruption) and topically (post eruption) by increasing tooth resistance to acid dissolution, by promoting remineralisation and by inhibiting the cariogenic microbial process.

5.2. Pharmacokinetic Properties

Fluoride is absorbed locally by the teeth. When swallowed, fluoride is absorbed rapidly and extensively (90-100%). Peak fluoride plasma levels are achieved within 30 to 60 minutes. Fluoride is widely distributed through the body and concentrates in the bone and tooth. About 50% of the intake is stored. Excretion is primarily through the kidneys with less than 10% being excreted in the faeces and less than 1% in sweat and saliva.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans beyond the information included in other section of the SPC.

6.1 List of Excipients

Poloxamer 407
Glycerol (E422)
Saccharin Sodium (E954)
Sorbitol, liquid(non-crystallising)
Propylene Glycol
Benzyl Alcohol
Potassium Sorbate
Citric Acid, Anhydrous
Levomenthol
Food Blue No. 5 (E131)
Flavour
Purified Water

6.2. Incompatibilities

Not applicable

6.3 Shelf Life

4 years
3 months after opening

6.4. Special Precautions for Storage

No special requirements.

6.5 Nature and Contents of Container

400 ml clear polyethylene terephthalate, round bottles with a tamper-evident white polyethylene screw cap.

6.6. Instructions for Use, Handling and Disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Colgate-Palmolive (UK) Limited
Goldsworth Place
1 Forge End
Woking
Surrey
England
GU21 6DB

8. MARKETING AUTHORISATION NUMBER

PL 00049/0012

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

12th February 1976 / 10th September 2003

10 DATE OF REVISION OF THE TEXT

03/07/2024