IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA0329/001/001
Case No: 2053168

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Pierre Fabre Medicament

45 Place Abel Gance, **92100 Boulogne**, **Cedex**, **France**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Eludril Mouthwash 1 mg/ml

the particulars of which are set out in the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **21/07/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Eludril Mouthwash 1 mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains chlorhexidine digluconate solution 0.005 ml (corresponding to 1 mg chlorhexidine digluconate).

The content of chlorhexidine digluconate per ml when diluted as recommended is 0.22mg/ml - 0.33mg/ml

Excipients: contains Cochineal Red A (E124) 0.003g/100 ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Mouthwash
Clear, pink liquid with an odour of menthol.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct in the topical prophylaxis and management of inflammation and minor infections of the mouth and oral pharynx, including use after operative or dental procedures in the oropharynx.

4.2 Posology and method of administration

Eludril is contraindicated in infants and children under six years of age: see section 4.3.

As a mouthwash, dilute 10 to 15 ml in the measuring-cup provided for this purpose and fill with lukewarm water to the upper line and use as a mouthwash or a gargle two or three times a day.

Route of administration
Oromucosal use. (This product is not intended to be swallowed).

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Use in infants and children less than 6 years of age.
- Use with anionic agents: see section 4.5.

4.4 Special warnings and precautions for use

- Cochineal red A can cause allergic type reactions including asthma (allergy is more common in those people who are allergic to aspirin).
- For oral use only.

- Keep out of the eyes. If the mouthwash comes into contact with the eyes, wash out promptly and thoroughly with water.
- Do not swallow.

If there is evidence of irritation or aggravation of the condition, the doctor or dentist should be consulted.

Discoloration of the tongue, teeth and silicate or composite restorations may occur. This stain is not permanent and can largely be prevented by brushing with a conventional toothpaste daily before using the mouthwash or, in the case of dentures, cleansing with a conventional cleanser.

If symptoms persist for more than 5 days and/or in the event of concomitant fever, treatment must be re-assessed.

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine is incompatible with anionic agents which are usually present in conventional toothpastes.
Therefore, thorough rinsing of the mouth, after toothbrushing with toothpaste, should be done before using Eludril mouthwash: see section 4.3.

4.6 Pregnancy and lactation

There are no adequate data from the use of chlorhexidine digluconate in pregnant or lactating women. Therefore, use during pregnancy or lactation should be avoided unless under the guidance of a medical practitioner.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Body system	**Adverse reactions (frequency not known)**
Immune system disorders	Hypersensitivity
Nervous system disorders	Dysguesia: may occur on initial use of the mouthwash. This disappears after treatment discontinuation
Gastrointestinal disorders	Tongue discolouration (see section 4.4) Tooth discolouration (see section 4.4) Parotid gland enlargement

4.9 Overdose

Overdose is not expected under normal conditions of use of this solution as a mouthwash.
Should accidental ingestion occur chlorhexidine when taken orally is poorly absorbed. Systemic effects are unlikely even if large volumes are ingested however, if chlorhexidine passes into the general system, signs of neurological toxicity may develop. These must be treated in a specialised environment. Gastric lavage may be advisable using milk, raw egg, gelatin or mild soap. Employ supportive measures as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-infectives and antiseptics for local oral treatment,
ATC code: A01AB03

Broad spectrum antibacterial (gram + and gram -) and anti-fungal product with extended bactericidal activity on buccal mucosa.

5.2 Pharmacokinetic properties

Very weak systemic absorption, distribution mainly via liver and kidneys; little metabolism (no degradation of the molecule). Elimination mainly in faeces (99.5 % of the ingested dose)

5.3 Preclinical safety data

No information further to that contained in other sections of the SPC is included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorobutanol hemihydrate
96% (v/v) ethanol
Glycerol
Docusate sodium
Alcoholic solution of mint essence
Levomenthol
Cochineal red A (E124)
Purified water

6.2 Incompatibilities

See section 4.5.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30^{o}C

6.5 Nature and contents of container

Type III glass bottle closed with an aluminium screw cap or PE cap fitted with an LDPE sealing ring, or PET bottle, closed with an aluminium cap or PE cap fitted with a LDPE sealing ring and a measuring cup with either printed measurements or engraved measurements.

Pack sizes: 90ml, 200ml, and 500ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Pierre Fabre Medicament
45 Place Abel Gance
92100 Boulogne
Cedex
France

8 MARKETING AUTHORISATION NUMBER

PA 329/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 June 1999

Date of last renewal: 25 June 2009

10 DATE OF REVISION OF THE TEXT

July 2010