



SUMMARY OF PRODUCT CHARACTERISTICS

PRODUCT SUMMARY

1. NAME OF THE MEDICINAL PRODUCT

Luborant

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.8ml contains Sodium Fluoride BP 0.003mg.

3. PHARMACEUTICAL FORM

Oromucosal solution.
Pink viscous liquid with an odour of orange.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Saliva deficiency. Luborant is a saliva substitute for use in the management of conditions involving dryness of the mouth. These include xerostomia following radiotherapy or during treatment with anti-depressants or anxiolytics, and other conditions involving a decrease in production of saliva, such as Sjögren's disease.

4.2 Posology and method of administration

Luborant is for oral use.
Adults, including the elderly: Two or three single applications orally up to four times daily or as directed by the physician. The average dose per application is 0.8ml of the product.

4.3 Contraindications

Hypersensitivity to sodium fluoride.

4.4 Special warnings and precautions for use

Mottling of dental enamel has occurred in association with use of Sodium Fluoride in larger amounts than those contained in the dosage recommended for Luborant.
Do not exceed the stated dose.
The contents should be discarded if not used before a date one month after the date of opening.

4.5 Interactions with other Medicinal products and other forms of Interaction

None known.

4.6 Pregnancy and lactation

There is no known or perceived hazard for use in pregnancy or lactation at the dosage recommended.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None stated.

4.9 Overdose

There are no reports of overdosage. Serious symptoms are unlikely following acute overdosage.

5. Pharmacological Properties**5.1. Pharmacodynamic properties**

Potassium Chloride]	Salts normally found in saliva.
Magnesium Chloride]	Electrolyte concentration close to whole
Calcium Chloride]	saliva. No precise pharmacological
Potassium Phosphate Dibasic]	activity other than electrolyte
Potassium Phosphate Monobasic]	replacement in oral cavity.

Sodium Fluoride: used for the prophylaxis of dental caries. It renders the dentine and enamel of the teeth more resistant to acid.

5.2. Pharmacokinetic properties

Luborant is applied topically to the oral mucous membrane for its local effects within the oral cavity. Although the individual constituent salts may undergo gastro-intestinal absorption, their concentrations in the daily dosages recommended for Luborant represent only a small percentage of the recommended daily human requirements of these salts and cannot, therefore, be expected to influence normal fluid or electrolyte balance.

5.3. Preclinical safety data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Potassium Chloride
Magnesium Chloride
Calcium Chloride
Potassium Phosphate Dibasic
Potassium Phosphate Monobasic
Sodium Parabens
Sodium Carboxymethylcellulose
Orange Flavour IFF VX 1997
Carmoisine Red CI 14720 E122
Sorbitol (70% w/v)
Hydrochloric Acid
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened: 24 months
Opened: 1 month

6.4 Special precautions for storage

Keep in outer carton.
Do not store above 25°C.

6.5 Nature and Contents of Container

60ml high density polyethylene bottle with a pump action applicator packed in cardboard cartons to contain 1 x 60ml and 6 x 60ml bottles.

6.6 Instructions for use, handling and disposal

Contents to be discarded if not used before a date one month after the date of opening.

ADMINISTRATIVE DATA

7. MARKETING AUTHORISATION HOLDER

Antigen International Ltd.
Roscrea
Co. Tipperary
Ireland

8. MARKETING AUTHORISATION NUMBER

PL 02848/0123

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10th January 1990 / 24th February 1999

10. DATE OF (PARTIAL) REVISION OF TEXT

October, 2003.