

1. NAME OF THE MEDICINAL PRODUCT

Luborant.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.8ml contains 0.003mg of Sodium Fluoride BP

Nipasept Sodium 1.600mg per 0.8 ml contains mixture of sodium hydroxybenzoates which is comprised of sodium p-hydroxybenzoate max. 0.064mg, Sodium Methyl 4-Hydroxybenzoate (E 219) 1.088mg to 1.216mg per 0.8 ml; Sodium Ethyl 4-hydroxybenzoate (E 215) 0.208mg to 0.288mg per 0.8 ml and Sodium Propyl 4-hydroxybenzoate (E 217) 0.128mg to 0.208mg.

3. PHARMACEUTICAL FORM

Oromucosal solution.

Pink viscous liquid with as odour of orange.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Saliva deficiency. Luborant is a saliva substitute for the management of conditions involving dryness of the mouth. These include xerostomia following radiotherapy or during treatment with antidepressants or anxiolytics, and other conditions involving a decrease in production of saliva, such as Sjogren'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 Contra-indications

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 overdose. Serious symptoms are unlikely following acute overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Potassium Chloride]	Salts normally found in saliva
Magnesium Chloride hexahydrate]	Electrolyte concentration close to whole
Calcium Chloride dihydrate]	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 concentration in daily dosage recommended for Luborant represents only a small percentage of the recommended daily human requirements of these salts and can not, 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 hexahydrate
Calcium Chloride dihydrate
Potassium Phosphate Dibasic
Potassium Phosphate Monobasic

Nipasept Sodium
Sorbitol solution 70% Non-crystallizing
Sodium carboxymethyl cellulose
Orange Flavour IFF VX 1997
Carmoisine Red CI 14720 E122
Hydrochloric Acid
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

Unopened : 2 years
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 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Limited,
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8. MARKETING AUTHORISATION NUMBER

PL 12762/0227

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

10th January 1990/24th February 1999

10. DATE OF (PARTIAL) REVISION OF THE TEXT

December 2009