

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Endekay Daily Fluoride Mouthrinse

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Fluoride BP 0.05% w/v

Excipients with known effect:

Sorbitol 101.64 mg/ml

Ethanol 60.37 mg/ml

Sodium benzoate 1.02 mg/ml

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Mouthrinse Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

An aid to the prevention of dental caries. To strengthen tooth enamel to resist decay.
To help resolve early caries lesions by promoting remineralisation.

4.2 Posology and method of administration

Adults and children over 6 years of age:

Half fill measuring cap and rinse teeth thoroughly for one minute and spit out. Use only one daily.

4.3 Contraindications

Hypersensitivity to sodium fluoride or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Not for use by children under six years of age. Do not swallow. Use only once daily.

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

Endekay Daily Fluoride Mouthrinse contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This medicine contains 755 mg of alcohol (ethanol) in each daily dose which is equivalent to 60.37 mg/ml. It may cause burning sensation on damaged skin.

This medicine contains 1.02 mg/ml of Sodium benzoate. Sodium benzoate may cause local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, Pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None at recommended dose.

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 at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Doses of fluoride of 5mg/kg (equivalent to 11mg/kg sodium fluoride) and greater may cause serious or life-threatening symptoms. Severe nausea, vomiting and diarrhoea have been reported.

Electrolyte disturbances including hypocalcaemia can occur, followed by rhythm disturbances and circulatory collapse.

Life-threatening symptoms may occur several hours after apparent recovery. Fatalities have been reported.

Treatment

Fluoride is rapidly absorbed from the stomach and intestines. Absorption of fluoride may be reduced by the oral administration of milk (minor effect) or stomach antacid tablets containing e.g. aluminium hydroxide or calcium/ magnesium.

Monitoring of serum Ca and administration of IV calcium gluconate in case of hypocalcaemia is necessary in cases of potentially severe poisoning. Urea, LFTS and other electrolytes should be monitored also. If symptoms occur, appropriate supportive measures should be employed.

Patients should be observed for several hours after ingestion even if there had been vomiting.

Contact the National Poisons Information Service (NPIS) for specific advice, especially for cases of severe poisoning.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Caries prophylactic agents

ATC code: A01AA01

Sodium fluoride in solution in a mouthwash reduces the incidence of caries. It helps to resolve early caries lesions and strengthens tooth enamel to resist decay by promoting remineralisation.

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

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water

Sorbitol solution

Sodium saccharin

Sodium benzoate

Poloxamer 407

Peppermint oil

L-menthol

Ethanol (96%)

Patent Blue V (E131)

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

PET bottle with HDPE or polypropylene cap containing 250ml, 400ml or 500ml.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Tillomed Laboratories Limited

220 Butterfield

Great Marlings

Luton

LU2 8DL

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 11311/0799

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

15 March 1999/3 March 2011

10 DATE OF REVISION OF THE TEXT

27/06/2025