New Zealand Datasheet

1 PRODUCT NAME
FluoroDose

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
1 ml of suspension contains 50 mg sodium fluoride equivalent to 22.6 mg of fluoride.

Excipient with known effect: denatured alcohol, xylitol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Whitish, opaque, dental suspension available in five flavours, mint, bubble gum, cherry, caramel and melon.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
For the prevention of caries in children and adults as part of a comprehensive control program. For the:

- prevention of recurring (or marginal) caries
- prevention of progression of caries
- prevention of decalcification around orthodontic appliances
- prevention of pit and fissure (occlusal) caries

For the desensitization of hypersensitive teeth as part of a treatment regimen which includes the daily use of a suitable toothpaste.

4.2 Dose and method of administration
FluoroDose 50mg/ml Dental Suspension is to be applied by the dentist. Before applying FluoroDose, excess plaque should be removed and the teeth dried. FluoroDose is applied as a thin layer to the most susceptible areas of dentition using a brush, probe or swab.

Recommended dosage for single application:

- For milk teeth: up to 0.25ml (= 5.65mg fluoride)
- For mixed dentition: up to 0.40ml (= 9.04mg fluoride)
- For permanent dentition: up to 0.75ml (= 16.95mg fluoride)
- For caries prophylaxis: the application is usually repeated every 6 months but more frequent applications (every 3 months) may be made.
- For hypersensitivity: 2 or 3 applications should be made within a few days.

The patient should not brush the teeth or chew food for 4 hours after treatment.

If necessary, the teeth should be cleaned, especially at the sites most susceptible to caries. When groups of patients (e.g. children) are to be treated, they should clean the teeth themselves using a toothbrush.

To start, clear one or two quadrants of excessive saliva using an air syringe (or dabbing with cellulose). FluoroDose 50mg/ml Dental Suspension is applied from a single dose tray using the supplied brush using the same technique. The next quadrants are then treated in the same manner. It is advisable to begin by applying the dental suspension to teeth in the lower jaw

before too much saliva collects and interferes. It may not be necessary to paint the lingual surfaces since these are generally more caries resistant; FluoroDose should preferably be applied to those spots most susceptible to caries attack.

For application to proximal surfaces, use the applicator of choice and apply a small amount of FluoroDose between adjacent teeth. The dental suspension should be applied from both sides of the interproximal space and occlusally.

For fissures, a drop of Fluorodose should be spread along the fissure using the applicator brush. Edges of fillings and crowns and hypersensitive tooth necks can be treated in the same way. The smooth surfaces of the teeth should be treated when caries activity is high, particularly if decalcification is evident. The applicator brush should be placed tangentially to the teeth and FluoroDose distributed appropriately.

Areas around fixed orthodontic devices can also be treated with Fluorodose using the brush or similar applicator.

The whitish colour of FluoroDose facilitates its application and control. FluoroDose sets in the presence of saliva. The effect of FluoroDose depends upon the prolonged activity of the Fluoride. The dental suspension film should not be removed prematurely. Patients should be advised not to brush their teeth or chew food for at least 4 hours after treatment; during this time, soft foods and liquids may be consumed. However, if you need to, the dental suspension layer can easily be removed by brushing and rinsing.

4.3 Contraindications

Hypersensitivity to colophony and/or any other constituents.
Ulcerative gingivitis.
Stomatitis.
Bronchial asthma.

4.4 Special warnings and precautions for use

Application of FluoroDose 50mg/ml Dental Suspension to the whole dentition should not be carried out on an empty stomach.

On the day when FluoroDose has been applied, no high dose Fluoride preparations, such as Fluoride gels, should be used. The administration of Fluoride supplements should be suspended for several days after applying FluoroDose. Prolonged daily ingestion of excessive fluoride may result in varying degrees of fluorosis.

4.5 Interaction with other medicinal products and other forms of interaction

The presence of alcohol in the FluoroDose formula should be considered.

4.6 Fertility, pregnancy and lactation

As this product contains 30% of ethanol (each dose contains up to 0.2g of alcohol), it is recommended to avoid its use in pregnant women and during lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects:

Gastrointestinal disorders:

Very rare (<1/10,000): Stomatitis, gingivitis ulcerative, retching, edema in mouth and nausea may occur in sensitive (allergic) individuals - if necessary, the dental suspension layer can easily be removed from the mouth by brushing and rinsing.

Skin and subcutaneous tissue disorders:
Very rare (<1/10,000): Irritation in sensitive individuals, angioedema

Respiratory, thoracic and mediastinal disorders:
Very rare/Isolated report (<1/10,000): Asthma

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose
In very high doses, Fluoride has an acute toxic action through inhibition of enzymes resulting in hypocalcaemia. Doses of several milligrams of Fluoride per kg body weight may cause nausea vomiting and diarrhoea. Tetany and convulsions can occur, as well as cardiovascular disorders. The dental suspension layer can easily be removed from the mouth by brushing and rinsing.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Stomatological preparations, caries prophylactic agents ATC code: A01A A01

Sodium Fluoride applied topically after tooth eruption reduces caries by inhibiting de-mineralization and promoting re-mineralization of the tooth surface and by inhibiting the cariogenic microbial process. FluoroDose 50mg/ml dental suspension also reduces dentinal hypersensitivity.

In the management of dental erosion associated with the frequent consumption of acidic beverages or gastric reflux, high concentration topical Fluoride agents are considered to be of value. FluoroDose is at least as effective as 2% Sodium Fluoride Solution in inhibiting erosion *in vitro*.

5.2 Pharmacokinetic properties
After oral administration, Fluoride absorption is rapid and extensive (90-100%) with peak Fluoride plasma levels reached within 30 to 60 minutes after ingestion. Fluoride is widely distributed through the body and concentrates in bone and teeth. About 50% of Fluoride is stored. Excretion is primarily through the kidneys with less than 10% being excreted in the feces and less than 1% in sweat and saliva.

FluoroDose covers teeth with a film of suspension which hardens in the presence of saliva and then persists, and which over the following hours causes Fluoride to accumulate at a measurable depth in the tooth enamel. Due to the slow release of Fluoride, the exposure level would be well below the level that could cause toxic signs and symptoms in children.

Doses of fluoride associated with dental fluorosis and risk of bone fracture would be well above the expected exposure level from FluoroDose dental suspension.

5.3 Preclinical safety data

The product is used under total control of the dentist and the amount of Fluoride introduced to the patient at one time is within acceptable safety limits. The recommended doses are up to 0.75ml for permanent dentition.

Treatment is recommended every 6 months or a maximum of every three months. For hypersensitivity 2-3 applications are recommended within a few days. These levels of Fluoride introduced are again within acceptable safety limits.

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, carcinogenic potential and toxicity to reproduction and development. The results of in vitro and in vivo genotoxicity studies are mixed. The significance of these findings to man are unclear.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Denatured Alcohol
Beeswax
Titanium dioxide
Colophony
Xylitol
Sucralose
Flavorings
FD&C Red Dye #40

6.2 Incompatibilities

None known

6.3 Shelf life

Unopened: 2 years.

6.4 Special precautions for storage

Do not store above 25ºC. Do not refrigerate, do not freeze.

6.5 Nature and contents of container

FluoroDose is supplied in single-use trays.
Boxes of 120, 600, 1200 x 0.3ml heat-sealed polypropylene trays.
A combination pack of multiple flavours is also supplied in single-use trays in boxes of 40, 120 or 600 units.

6.6 Special precautions for disposal

There are no particular precautions for disposal.

Instruments, clothing, etc. which comes into contact with FluoroDose can be cleaned with alcohol.

7 MEDICINE SCHEDULE

Prescription Medicine.

8 SPONSOR

CARSL Consulting
PO Box 766
Hastings
Ph (06) 875 0979

for Centrix Inc

Distributor:
Healthcare Essentials
120 Tirangi Road
Rongotai
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PO Box 14421
Wellington 6241

Telephone: 0508 802 55 77

9 DATE OF FIRST APPROVAL

12 September 2024

10 DATE OF REVISION OF THE TEXT

16 August 2024

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information