New Zealand Datasheet

1 PRODUCT NAME
Topamine

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Silver diamine fluoride 38%w/v (equivalent to silver 25%w/v and fluoride 4.5%)

3 PHARMACEUTICAL FORM
Topamine is a topical solution for dental use.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
For the prevention and treatment of dental caries.

For the relief of dentinal hypersensitivity.

4.2 Dosage and method of administration
Isolate the affected area of the tooth with cotton rolls or protect the gingival tissue of the affected tooth with petroleum jelly. Alternatively, a rubber dam can be used to isolate the area.

Clean and thoroughly dry the affected tooth surface.

For up to 5 treated sites per patient, dispense 1 drop (20 microlitres = 1.3 mcg fluoride) of solution into a disposable dappen dish. Transfer material directly to the tooth surface to be treated with a micro applicator.

Air dry. If needed, one or two reapplications may be administered at intervals of one week.

4.3 Contraindications
This product is contraindicated in patients with ulcerative gingivitis or stomatitis or known sensitivity to silver or other heavy-metal ions.

Patients with more than 6 affected sites, patients having had full mouth gingivectomies and patients showing abnormal skin sensitisation in daily circumstances are recommended for exclusion.

4.4 Special warnings and precautions for use
This product is intended for local application only. Not for ingestion.

Protect the patient's eyes. Use caution to avoid contact with skin copiously with water and immediately seek medical attention.

Avoid contact with equipment and surfaces as permanent staining may occur.

Precautions
Minimise product contact with gingiva and mucous membranes by using recommended amounts and careful application. Topamine may cause reversible short-term irritation. When applying Topamine to areas near the gingiva, apply petroleum jelly or cocoa butter and use cotton rolls to protect the gingival tissues. Alternatively, a rubber dam can be used to isolate the area.

If accidental contact occurs to non-targeted areas, thoroughly wash the area with water, saline solution or ~3% Hydrogen Peroxide. Topamine has been coloured blue to help identify the presence of solution when dispensing. Always use caution to avoid transferring the solution from gloved hands to other surfaces.

Topamine does not normally stain enamel or burnished dentin. Advise patient that soft dentin or margins of composite restorations may be stained. Staining may be reversed by gentle polishing with tincture of iodine (weak iodine solutions).

Information for Patients
Advise patients that air-drying and product application can cause momentary transient pain to hypersensitive areas. Topamine has not been shown to cause pulpal necrosis even when applied to soft dentin.

4.5 Interaction with other medicines and other forms of interaction
No interactions with other medicinal products are known.

4.6 Fertility, Pregnancy and lactation
Pregnancy
It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount administered is incorporated in foetal tissue. Animal studies (rats, mice, rabbits) have shown that fluoride is not a teratogen. Fluoride has been taken by a limited number of pregnant women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effect on the human foetus having been observed. Epidemiological studies conducted in areas with high levels of naturally fluoridated water showed no increase in birth defects. Heavy exposure to fluoride during in utero development may result in skeletal fluorosis, which becomes evident in childhood.

Breast feeding
It is not known if fluoride is excreted in breast milk. However, many drugs are excreted in milk and caution should be exercised when products containing fluoride are administered to lactating women.

Fertility
No information available.

4.7 Effects on ability to drive and use machines
No effects expected.

4.8 Undesirable effects
Transient irritation of the gingiva has rarely been reported.

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 https://pophealth.my.site.com/carmreportnz/s/.

4.9 Overdose
For advice on the management of overdose, contact the Poison Information Centre on 0800 746766.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Stomatological preparations, caries prophylactic agents - ATC code: A01A A01

Topamine provides Silver Diamine Fluoride complex, the most active and soluble form of silver ion, which on application to the exposed dentinal sites, plates out Silver to seal the tubules and relieve dentinal hypersensitivity.

Topamine applied topically after tooth eruption reduces caries by inhibiting demineralisation and promoting remineralisation of the tooth surface and by inhibiting the cariogenic microbial process.

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.

This medicine has been given a provisional consent under Section 23 of the Act. This means that further evidence on this medicine is awaited.

5.2 Pharmacokinetic properties

The action of the product is through the interaction of the reactive silver ion plating out silver (metal) on the dentine's hydroxyapatite and forming a blockage within the dentinal tubules to stop transitions which are causing hypersensitivity reactions.

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 faeces and less than 1% in sweat and saliva.

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 Topamine.

5.3 Preclinical safety data

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ammonia solution 30% (for pH adjustment)
Brilliant Blue
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage
Store at or below 30°C protect from light.

6.5 Nature and contents of container
Topamine solution is packed in 5mL white LDPE plastic, drip proof, dropper bottle.

6.6 Special precautions handling and disposal
Disposal
Disposal Method:
Neutralize with slurry of calcium hydroxide (monitor heat generation) and pH of supernatant solution should range from 5.8-8.6. Monitor F and N content before disposal. Follow local, regional, state and national guidelines.

Any unused material should be disposed according to local disposal regulations

Precautions for Handling
Store in original packaging in a cool, dark place.

Replace cap immediately after use.

Use liquid as soon as dispensed.

May stain equipment surfaces brown or black. Refer to the following for stain removal techniques:

Skin: wash immediately with water, soap, ammonia solution or iodine tincture and then rinse thoroughly with water. Do not use excessive methods in an attempt to remove difficult stains from skin. Staining on skin will eventually fade in 1 to 3 weeks.

Clothing/Benchtops/Floors/Instruments/Equipment Surfaces:
Use the same procedures as with stained skin. Difficult stains may be treated with sodium hypochlorite if surface will allow.

If Topamine is dispensed into a separate container, be sure to wash or thoroughly wipe the container clean immediately after use with a disposable tissue or wipe.

7 MEDICINE SCHEDULE
Prescription Medicine.

8 SPONSOR
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9 DATE OF FIRST APPROVAL
5 September 2024

10 DATE OF REVISION OF THE TEXT

21 August 2023

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information