

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Colgate TOTAL Pro Gum Health Toothpaste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Triclosan 0.30 % w/w.

Sodium Fluoride 0.32 % w/w (1450 ppmF).

Excipients with known effect

Peppermint flavour (contains Propylene Glycol).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Toothpaste

White toothpaste with flavour and odour of mint.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

To reduce dental caries.

To improve gingival health by:

1. Significantly reducing the formation of plaque and calculus.
 2. Significantly reducing existing levels of gingival bleeding and inflammation.
- To reduce the progression of periodontitis.

4.2 Posology and method of administration

Adults

The usual dosage is to apply a ribbon of toothpaste across the head of the toothbrush (approximately 1.0 g) and to brush the teeth for one minute twice daily.

Paediatric population

For children under 6, do not use unless directed by a dentist or a physician. If using fluoride supplements consult your dentist.

Elderly

As for adults.

Renal or hepatic insufficiency

Dose adjustment is not required in patients with renal or hepatic insufficiency.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

May cause skin irritation.

Paediatric population

For children under 6, do not use unless directed by a dentist or a physician. If using fluoride supplements, consult your dentist.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

It is important to note that as for any fluoride containing toothpaste, in children under systemic fluoride therapy, it is important to evaluate the total exposure to fluoride (fluorosis).

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data on pregnant women (less than 300 pregnancy outcomes) from the use of fluoride/triclosan in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). The use of Colgate TOTAL Pro Gum Health may be considered during pregnancy, if necessary.

Lactation

No effects of fluoride/triclosan have been shown in breastfed newborns/infants of treated mothers. Colgate Total Pro Gum Health can be used during breast-feeding.

Fertility

There is no information about the possible effects on fertility. No harmful effects are expected.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The undesirable effects reported with Colgate Total Pro Gum Health during post-marketing surveillance are shown in the table below. They are common for fluoride containing toothpastes. They are listed by System-Organ Class (SOC) and in order of frequency, using the following convention: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$); not known (cannot be estimated from the available data).

SOC	Frequency	Adverse drug reaction
Immune system disorders	Not known	Hypersensitivity (allergic reactions)
Gastrointestinal disorders	Not known	Oral Mucosal exfoliation Dry mouth Stomatitis Hypoaesthesia oral

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Not applicable.

Use of this type of product would not be expected to result in an overdose.

No acute effects would be expected from the low level of triclosan (489 mg in a 125 ml tube). Even in the extreme case of prolonged exposure, serious adverse effects would not be expected from triclosan.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Caries prophylactic agents, ATC code: A01AA51

Triclosan: Triclosan is a broad-spectrum non-ionic antibacterial with activity against both aerobic and anaerobic gram-positive and gram-negative microbes. It is widely employed as a disinfectant and as an anti-bacterial in external use OTC (over the counter) products. In Colgate TOTAL Pro Gum Health Toothpaste it is combined with a copolymer which enhances the delivery of triclosan to the site of action.

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

5.2 Pharmacokinetic properties

Triclosan: When administered in a dentifrice by toothbrushing, salivary and plaque triclosan levels range between 1-6 ppm and 25 ppm respectively at 1-2 hours after using a 0.3% dentifrice. Following usage of a dentifrice containing up to 0.6% triclosan, mean blood levels range between 15 to 25 ppb.

Blood levels of triclosan in subjects brushing with a dentifrice are about 14 per cent of those in subjects who directly ingested an aqueous solution in an equivalent dose level.

Sodium Fluoride: After oral administration, fluoride absorption is rapid and extensive with (90 - 100%) peak fluoride plasma levels reached within 30 to 60 minutes after ingestion. Fluoride is widely distributed through the body and concentrates in the bone and teeth. About 50% of fluoride absorbed 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

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

Triclosan

Triclosan is well absorbed from the GI tract following oral exposure and has limited buccal absorption in humans following normal toothpaste use. In animal studies, Triclosan is not acutely toxic via the oral route of administration. It was also found to not be teratogenic nor a reproductive toxicant in multiple species. Moreover, Triclosan is nongenotoxic and not considered to be carcinogenic. The wealth of safety data suggest that the use of 0.3% Triclosan in Colgate Total Pro Gum Health does not pose a safety concern.

Sodium fluoride

Fluoride is not expected to be genotoxic, carcinogenic or teratogenic in humans. The results of genotoxicity testing of sodium fluoride are mixed. However, if genotoxicity was occurring and being manifested in the mammalian systems, it would be expected to be seen as adverse effects on offspring or as tumor formation in chronically exposed animals. The lack of teratogenicity or embryotoxicity and the preponderance of evidence against a carcinogenic effect of fluoride lends greater weight to the absence of effective genotoxicity for fluoride compounds present in Colgate Total Pro Gum Health.

Prolonged daily ingestion of excessive fluoride may result in varying degrees of fluorosis. By age 8, there is no longer a risk for dental fluorosis. Doses of fluoride associated with dental fluorosis and risk of bone fracture would be well above the expected exposure level from Colgate Total Pro Gum Health.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Silica Dental Type
Sorbitol, liquid(70%) non-crystallising
Purified water
Poly (methyl vinyl ether) / maleic acid copolymer
Sodium hydroxide (25% solution)
Sodium laurilsulfate
Mint Flavour (contains Propylene Glycol)*
Carmellose sodium
Titanium dioxide (E171)
Iota Carrageenan
Saccharin sodium
* contains: Peppermint oil, Levomenthol, Synthetic mint flavour, Anethole, Spearmint oil and Synthetic cooling flavour

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Colgate TOTAL Pro Gum health Toothpaste is packaged in laminated polyethylene/aluminium/polyethylene lay down tubes with polypropylene caps.
Pack sizes: 19, 50, 75, 100, 125 and 150 ml.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Colgate-Palmolive A/S
Bredevej 2 A
Virum

Hovedstaden 2830
Denmark

8 MARKETING AUTHORISATION NUMBER

PA22581/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1999

Date of last renewal: 1st April 2009

10 DATE OF REVISION OF THE TEXT

May 2019