Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Colgate TOTAL Pro Gum Health Tartar Control Toothpaste

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients
Triclosan 0.30% w/w.
Sodium Fluoride 0.32% w/w (1450ppm Fluoride).

Excipients
Peppermint flavour (contains Propylene Glycol).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Toothpaste.
A white toothpaste with odour and flavour 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

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

Children under 7, use a pea-sized amount for supervised brushing to minimise swallowing. If using fluoride supplements, consult your dentist.

4.3 Contraindications

None known.

Individuals with known sensitivities should consult with their dentist before using.

4.4 Special warnings and precautions for use

Children under 7, use a pea-sized amount for supervised brushing. If using fluoride supplements, consult your dentist.
May cause skin irritation.

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 using systemic fluoride therapy, it is important to evaluate the total exposure to fluoride (fluorosis).

4.6 Fertility, pregnancy and lactation

Use of this product is not contraindicated during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

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

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 Tartar Control 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 demineralization 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

Triclosan: In subchronic oral ingestion studies with rats dentifrices containing triclosan were administered for 13 weeks at levels that are conservatively up to 100 times expected human use levels. Animals received daily doses of up to 12 mg/kg of triclosan and showed no indications of treatment related effects. This dose would be equivalent to 600 mg of triclosan in 50 kg human.

Ingestion of 125 ml of a toothpaste (approximately one tube) containing 0.3% triclosan would give an intake of approximately 489 mg and would not be expected to produce untoward effects.

Sodium Fluoride: The total amount of sodium fluoride in a 125 ml tube of Colgate TOTAL Pro Gum Health Tartar Control Toothpaste is 516 mg. This is within the acceptable limits for the amount to be dispensed at one time for safety purposes. Prolonged daily ingestion of excessive fluoride may result in varying degrees of fluorosis.

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
Sodium Hydroxide (25% solution)
Sodium Laurilsulfate
Peppermint flavour* (contains Propylene Glycol)
Carmellose sodium
Titanium Dioxide (E171)
Iota Carrageenan
Saccharin Sodium
* Contains: Menthol, Peppermint Oil, Anethole, Spearmint Oil, Cooling Flavour, Synthetic Mint Flavour, Lemon Oil, Cooling Agent

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three 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 Tartar Control Toothpaste is packaged in 19, 50, 75, 100, 125 and 150 ml lay down foil laminate tubes and 100, 125 and 150 ml stand-up-tubes consisting of three elements:

a) Conical shoulder with threaded neck manufactured from high density polyethylene,
b) Barrier material of polybutyl teraphthalate (PBT) or polyester teraphthalate (PET) below and inside the conical shoulder,
c) Cylindrical laminated tube body.

The lay down tube body is manufactured from 5-ply laminated webstock comprising from outside to inside:

Outer layer: Polyethylene,
Adhesion copolymer,

Aluminium foil,
Adhesion copolymer.
Inner layer: Polyethylene.

The stand-up-tube body is manufactured from polyethylene laminate comprising:

Medium density polyethylene,
Ethylvinyl alcohol barrier,
Medium density polyethylene.

The caps are manufactured from polypropylene and are either screw or snap-on.

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

PA22581/002/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 02 April 2004
Date of last renewal: 01 April 2009

10 DATE OF REVISION OF THE TEXT

May 2019