Safeguarding public health

MHRA

Public Assessment Report

Colgate Sensitive Care Toothpaste
(sodium monofluorophosphate and potassium citrate)

PL 00049/0054

Medicines and Healthcare products Regulatory Agency

COLGATE SENSITIVE CARE TOOTHPASTE
(sodium monofluorophosphate and potassium citrate)
PL 00049/0054

UKPAR

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Colgate Sensitive Care Toothpaste (sodium monofluorophosphate and potassium citrate)

PL 00049/0054

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Colgate-Palmolive (UK) Limited a Marketing Authorisation (licence) for the medicinal product Colgate Sensitive Care Toothpaste (PL 00049/0054). This is a general sale list (GSL) medicine for reducing tooth decay and pain associated with sensitivity.

Colgate Sensitive Care Toothpaste contains sodium monofluorophosphate and potassium citrate. Sodium monofluorophosphate is known for its protective effect against the process by which tooth decay occurs. Potassium citrate influences the ionic balance at the level of the pain receptor of the tooth.

This is an abridged application made under Article 10c [formerly Article 10.1(a)(i)] of EC Directive 2001/83 and is a duplicate of a previously granted licence for PL 00049/0031 (Colgate Sensitive Fresh Stripe Toothpaste). This licence is also held by Colgate-Palmolive (UK) Limited, granted 24th June 1994.

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of using Colgate Sensitive Care Toothpaste outweigh the risks, hence a Marketing Authorisation has been granted.

COLGATE WHITENING TOOTHPASTE
(sodium monofluorophosphate and potassium citrate)
PL 00049/0054

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Colgate Sensitive Care Toothpaste (PL 00049/0054) to Colgate-Palmolive (UK) Limited on 27 March 2006. The product is a general sale list (GSL) medicine.

This application was submitted as a simple abridged application under Article 10c [formerly Article 10.1(a)(i)] of EC Directive 2001/83 cross referring to PL 00049/0031 (Colgate Sensitive Fresh Stripe Toothpaste). The licence is held by Colgate-Palmolive (UK) Limited, granted 24th June 1994.

No new data were submitted for this simple application, nor were any necessary, as the data are identical to that of the previously granted cross-referenced product. As the cross-referenced product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

The product contains the active ingredients sodium monofluorophosphate and potassium citrate. Potassium influences the ionic balance at the level of the pain receptor of the tooth. 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.

The combination of sodium monofluorophosphate and potassium citrate in Colgate Sensitive Care Toothpaste is indicated for prevention and treatment of teeth sensitivity and caries.

PHARMACEUTICAL ASSESSMENT

PL number:	PL 00049/0054
Name of Product:	Colgate Sensitive Care Toothpaste
Active(s):	Potassium Citrate 5.53% w/w and sodium monofluorophosphate 1.14% w/w (1500 ppm F)
Company Name:	Colgate Palmolive (UK) Ltd.
E.C. Article:	10.1c (previously 10.1(a)(iii)
Legal Status:	GSL

Legal Basis

This is a simple abridged application for Colgate Sensitive Care Toothpaste, containing Potassium Citrate 5.53% w/w and sodium monofluorophosphate 1.14% w/w.

The application is submitted under Article 10c [formerly Article 10.1(a)(i)] of EC Directive 2001/83 as a duplicate of Colgate Sensitive Fresh Stripe Toothpaste containing the same active ingredients and amounts. The reference product licence is held by Colgate-Palmolive (UK) Limited, granted 24th June 1994 (PL 00049/0031).

Letters of consent

Neither a letter of consent nor a letter confirming agreement to manufacture has been supplied. These are not necessary as the cross reference licence is held by Colgate-Palmolive who is also the manufacturer.

Reference Product

There are no outstanding variations and renewal issues.
There are no outstanding issues with the reference product.

TSE

The MAA form (Section 2.6.2) indicates no ingredients in the product that are TSE susceptible.

Expert reports
The applicant has included a detailed Quality Overall Summary, Non clinical and Clinical Overviews in Module 2 of the application, written by appropriately qualified experts. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4.

These reports confirm the application to be identical with the reference product in all particulars.

The reports are accepted.

Product name

It is based on the company brand name and is acceptable.

Summary of Product Characteristics (SPC)

The SPC has been updated in line with regulation (EC) 726/2004 and is in line with the reference product.

Combined label-patient information leaflet

Combined label-leaflet mock-ups have been provided for 19ml, 50ml, 75ml and 100ml carton and tubes, together with 100ml stand-up packs.

MAA form

The sites of manufacture, assembly, QC and batch release are in line with the reference product. A satisfactory manufacturing licence is provided.

Section 4 Additional Information

Satisfactory

CONCLUSION

A marketing authorisation may be granted for this product.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

The data for this application is consistent with those previously assessed for the cross-referenced product and as such have been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

This application is identical to a previously granted application for Colgate Sensitive Fresh Stripe Toothpaste.

No new or unexpected safety concerns arose from this application.

The SPC and combined PIL-labelling are satisfactory and consistent with those of the cross-referenced product.

RISK-BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-referenced product. Extensive clinical experience with the active ingredients sodium monofluorophosphate and potassium citrate is considered to have demonstrated the therapeutic value of the compounds. The risk-benefit assessment is therefore considered to be favourable.

COLGATE SENSITIVE CARE TOOTHPASTE
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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application for Colgate Sensitive Care Toothpaste on 20th July 2004.
2	Following standard checks the MHRA informed the applicant that its application was considered valid on 4th August 2004
3	The MHRA's initial assessment of the submitted data was completed on 25th January 2005
4	Further information was requested from the company on 8th February 2005.
5	The MHRA received the response to further information request on 6th June 2005
6	Additional information was requested from the company on 28th June 2005.
7	The MHRA received the response to additional information request on 26th July 2005
8	Outstanding issues where raised on 19th August 2005.
9	The applicant submitted its response to outstanding issues on 5th December 2005
10	The MHRA completed its assessment of the application on 17th March 2006
11	The application was determined on 27th March 2006

COLGATE SENSITIVE CARE TOOTHPASTE
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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Colgate Sensitive Care Toothpaste

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Potassium Citrate	5.53% w/w
Sodium Monofluorophosphate	1.14% w/w (1500 ppm F)

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Toothpaste

A blue paste with a white stripe

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Prevention and treatment of teeth sensitivity and caries.

4.2. Posology and method of administration

For dental use.

Children from the moment they are capable of spitting out excess toothpaste (e.g. 6 years) and adults.

Place the usual amount of toothpaste on the toothbrush and brush twice a day (morning and after the last meal of the day).

There is no adjustment for renal or liver insufficiency, dialysis or concomitant disease, the drug is applied locally.

4.3. Contraindications

There are no known contraindications. Do not use in patients who are known to be sensitive to any of the ingredients.

4.4. Special warnings and precautions for use

There are no special warnings and precautions. The product is used in the same way as a regular toothpaste. Children under 7, use a pea-sized amount for supervised brushing. If using fluoride supplements, consult your dentist.

4.5. Interactions with other medicinal products and other forms of interaction

There are no known interactions with other drugs. 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. Pregnancy and lactation

There are no contraindications for use during pregnancy and lactation. The product is applied locally and rinsed after brushing.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

None described.

4.9. Overdose

The overdose effects are related to the bulk presented by the non-active ingredients and not to the active ingredients. Potassium is rapidly excreted by the kidneys and the fluoride levels are within acceptable limits (1500 ppm).

The management of overdose is either to dilute by drinking water or to vomit, but a physician should be contacted.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Colgate Sensitive Care belongs to the group of toothpastes with anti-sensitive properties and an anticaries effect (ATC code A01AA02). Potassium influences the ionic balance at the level of the pain receptor of the tooth. Fluoride is known for its protective effect against caries by acid microbial attack.

5.2. Pharmacokinetic properties

a) General characteristics of the active substances

Fluoride and potassium are absorbed locally by the teeth. If swallowed, both ions are absorbed and eliminated by the kidneys at the rate of 100% of the 'excess' potassium and 40 to 50% of the 'excess' fluoride, if any.

b) Characteristics in patients

In patients there are no variations with respect to confounding factors. Since the drug is applied topically there is no relationship with systemic levels and activity.

5.3. Preclinical safety data

There are no findings of relevance to the health professional, additional to those already included elsewhere in the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sorbitol 70%
Glycerol
Dental Type Silicas
Irradiated pasteurised water
Macrogol
Sodium laurilsulfate
Titanium dioxide
Carmellose Sodium
Xanthan gum
Sodium Saccharin
Fresh Spearmint Flavour 89-244 (Anethole, Eugenol, Menthol Levo, Peppermint Mixture Redistilled, Spearmint Mixture)
Colour E131.

6.2. Incompatibilities

None.

6.3. Shelf life

Three years.

6.4. Special precautions for storage

Do not store above 25ºC

6.5. Nature and contents of container

19, 50, 75 and 100 ml tubes of laminate polyethylene polymer with a screw flip-top of polypropylene.

100 ml stand up tubes of polyethylene with polypropylene closures.

100 ml dispenser pump of polypropylene with low density polyethylene piston.

6.6. Instruction for use and handling

None.

Administrative Data

7. MARKETING AUTHORISATION HOLDER

The holder of the Marketing Authorisation will be

Colgate-Palmolive (U.K.) Ltd
Guildford Business Park
Middleton Road
Guildford
Surrey GU2 8JZ
UK

8. MARKETING AUTHORISATION NUMBER

PL 00049/0054

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/03/2006

10 DATE OF REVISION OF THE TEXT

27/03/2006

COLGATE SENSITIVE CARE TOOTHPASTE
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Tube Labelling

Combined Carton Labelling and Patient Information Leaflet