



Healthy plaque
management



DECAPINOL® mouthwash and toothpaste
A new and intelligent way to manage gingivitis and prevent periodontitis.



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1.0 Product Description

Decapinol® is a novel, first in class aid for gingivitis and the prevention of periodontitis.

Delmopinol, a surface-active cationic agent is the key ingredient in Decapinol®. It is able to form a barrier that reduces surface tension on the teeth and gums and inhibits bacterial glycosyl transferases, preventing microbial adhesion and colonisation on their surface, thus hampering the adherence of bacteria and significantly slowing the formation of new plaque without altering the oral bacteria flora.

- Decapinol® (delmopinol) inhibits plaque formation by interfering with the process – working at the interface between dental plaque bacteria and the surface of the tooth/gingiva. Decapinol® has a significant effect in reducing plaque and penetrating existing plaque to destabilise it ⁽¹⁾
- Decapinol® prevents plaque adhering to the teeth ⁽²⁾
- Decapinol® also interferes with the glycosyl transferases, which are responsible for the production of polysaccharide (the glue or cement that is critical for plaque build up). This results in less cohesive and less adhesive plaque bacteria, making plaque easier to remove by conventional tooth brushing techniques ⁽²⁾

Decapinol® promotes a healthy balance of oral microflora and protects gently and safely against gingivitis. Decapinol® maintains a healthy level of plaque but prevents excessive build up and colonisation by harmful bacteria. This is similar to the pro-biotic approach taken when using pro-biotic lactobacillus-based yoghurts.

Decapinol® toothpaste contains Sodium Fluoride (NaF) 0.11% and Delmopinol 0.2%. Sodium Fluoride (NaF) is the most popular key ingredient in toothpaste to prevent cavities.

Decapinol 300ml PET bottle and Decapinol toothpaste 75ml PE tube are available from your wholesaler.

2.0 Disease Overview

Gingivitis is a gingival condition, that describes an inflammation of the gums (gingiva) and affects approximately 80-90% of the adult population ^(4,5). Plaque-associated gingivitis is an inflammation of the interdental and gingival margin that can be controlled using a healthy plaque management system.

Periodontitis is a more serious condition, and will arise, if the gingivitis is allowed to worsen and pathogenic bacteria colonise in the inter-gingival pockets. The structures that anchor the teeth to the bone are affected, causing tooth and bone loss.

Gingivitis always precedes periodontitis and prevention or treatment of gingivitis is considered an accepted method of preventing periodontitis ⁽¹⁾.

3.0 Indication

Decapinol® helps treat gingivitis and prevent periodontitis. It also helps remove and prevent plaque build-up on the teeth and gingiva that can lead to gingivitis and periodontitis. Decapinol® inhibits plaque formation in patients with gingivitis and serves as an adjunct to normal mechanical oral hygiene where this has proved inadequate.

4.0 Key Features and Benefits

Features	Benefits
<ul style="list-style-type: none"> ○ Contains the surfactant Delmopinol (0.2%) ○ Delmopinol prevents bacteria adhering to the gingiva, teeth and to each other ○ Delmopinol makes existing plaque unstable ○ Delmopinol's mode of action reduces re-establishment of plaque 	<ul style="list-style-type: none"> ○ Helps to reduce symptoms associated with gingivitis, e.g. bleeding gums, inflammation & the build up of plaque ○ Patients find plaque easier to remove by conventional brushing methods which results in improved oral hygiene ○ Helps prevent <i>further</i> adherence of plaque to the gingiva & dentition
<ul style="list-style-type: none"> ○ Proven long term safety & efficacy in large number of patients 	<ul style="list-style-type: none"> ○ Effective in treating and preventing gingivitis in the short, medium & long term
<ul style="list-style-type: none"> ○ Decapinol® does not kill <i>all</i> bacteria within oral cavity. Instead, it promotes a healthy balance of oral flora bacteria, which then protects the mouth from colonisation by pathogens 	<ul style="list-style-type: none"> ○ Helps to maintain bacteria, which is associated with healthy teeth & gingiva ○ Reduces the colonization of secondary pathological bacteria, which is associated with periodontal disease
<ul style="list-style-type: none"> ○ Decapinol® does not cause the semi-permanent tooth staining associated with other Chlorhexidine-based products 	<ul style="list-style-type: none"> ○ Decapinol® can be used long term, so not only treats but prevents gingivitis more effectively than CHX in practice ○ Lack of staining means patient compliance is high compared to CHX
<ul style="list-style-type: none"> ○ Negligible alcohol content 	<ul style="list-style-type: none"> ○ Anti-plaque mouthwash⁽⁶⁾ brands widely available in the market contain more than 10% alcohol ○ Research has shown a causal link to the level of alcohol in oral mouthwashes and oral cancer
<ul style="list-style-type: none"> ○ Unlike Chlorhexidine, does not interact 	<ul style="list-style-type: none"> ○ Patients can incorporate into normal oral

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with SLS ingredient contained in regular toothpaste	<ul style="list-style-type: none"> ○ hygiene routine ○ Efficacy is maintained
<ul style="list-style-type: none"> ○ Decapinol® toothpaste contains Delmopinol and NaF 	<ul style="list-style-type: none"> ○ Specially developed for an improved long term daily oral hygiene ○ Able to replace usual toothpaste

5.0 Side Effects

The side effects of Decapinol® are mild and temporary and are commonly associated with an numbing and/or a tingling sensation on the tongue. Changes in taste and a feeling of dry mouth can occur for a short while after each rinsing at the beginning of treatment. These side effects subside as treatment continues. Light staining can normally be removed by brushing the teeth.

6.0 Cautions

The use of Decapinol® is contra-indicated in patients with a known history of hypersensitivity to any of the ingredients, in patients with liver or kidney disorders, and in pregnant or breastfeeding women.

7.0 Supporting Data

Decapinol® has extensive supporting data comprised of 12 major clinical studies in over 1,300 patients.

A comprehensive database of published, supervised and unsupervised studies is available on Decapinol® Mouthwash and Toothpaste. Eight Phase III double blind, parallel group, placebo controlled clinical studies (published and unpublished) were conducted in five major European countries.

Five studies were pivotal, involving supervised rinsing and all addressed American Dental Association (ADA) requirements (Chlorhexidine (CHX) was used as a positive control). Three larger studies involving unsupervised rinsing were completed to test Decapinol's® safety aspects. One open study lasting 12 months was also completed to assess the safety and tolerability of Decapinol® in normal use.

In 2007 a meta-analysis was published (J Clin Periodontal 2007;34:58-65) and confirmed that in over 1,300 patients Decapinol® was effective and safe to use (from two weeks to 12 months) in both unsupervised and supervised studies.

These clinical studies confirm Decapinol® mouthwash and toothpaste are an effective, safe, well tolerated and innovative treatment for gingivitis and prevention against the onset of periodontitis.



The following table summarises the clinical studies and references undertaken on Decapinol®.

**Decapinol Clinical Studies Summary: Phase III (unpublished)
Data on file at Sinclair Pharma UK Ltd.**

No	Reference	Decapinol 0.2%	Decapinol 0.1%	Placebo	CHX	Duration
	Investigator, country, Reference code Publication reference	No. patients entered in study/no. patients analysed per protocol p values for Bleeding on probing (BoP) p values for plaque index				
1	Hugosen, Sweden C41/Supervised	40/38 P=0.005 Plaque P= NS BoP	40/37	40/39		2 mo
2	Bergenholtz, Sweden C42/Supervised	40/36 P=0.002 plaque P=0.009 BoP	44/41	39/36		2mo
3	Adriaens, Brussels C44/Supervised	50/41 P=0.002 Plaque P=0.010 GFF (Gingivitis)		51/40	53/40	5mo
4	Claffey, Eire C46/Unsupervised	156/112 P=0.0001 Plaque P=0.0002 Adjusted	157/113	157/134		3 mo
		BoP pp				
5	Van Steenberghe, Belgium C48/Unsupervised	150/109 P= 0.0001 Plaque P= 0.1097 Adjusted BoP pp	151/103	150/125		3 mo
6	Adriaens, Belgium C50 Open.	112/84				12 mo

Decapinol Clinical Studies (Published)

No.	Study	Indication	Patient population	Design	No. of patients	Study duration
7	Addy et al. J Clin Periodontol 2007; 34: 58-65	Gingivitis	Adults	Meta-analysis of 8 different randomised, double-blind, parallel group studies to evaluate Delmopinol 0.2% as mouthwash	467 (supervised rinsing) 913 (unsupervised rinsing) Total no. of patients 1380	From 2 to 6 months
8	Hase, Attstroem et al. J Clin Periodontol 1998;25:746-753	Gingivitis	Adults	A double blind, vehicle controlled monocentre study to examine the efficacy and safety of Decapinol mouthwash.	149	180 days
9	Hase, Attstroem et al. J Clin Periodontol 1998; 25:841-849	Gingivitis	Adults	A double blind, vehicle controlled monocentre study to evaluate the microbiological mouth flora in association with Gingivitis/Periodontitis and the treatment of Delmopinol	68	180 days
10	Hase et al. Eur J Oral Sci. 1995 Jun;103(3):172-8	Gingivitis	Adults	double-blind, placebo controlled randomized, clinical trial with cross-over design to study the efficacy and safety of Delmopinol hydrochloride solution (2 mg/ml), used with no other oral hygiene procedures	14	15 days
11	Hase et al. J Clin Periodontol 1995 Jul, 22 (7) 533-9	Plaque formation	Adults	Double-blind randomised clinical trial to evaluate the antibacterial efficacy and safety of Delmopinol	57	28 days
12	Lang, Hase et al. Oral Diseases 1998;4:105-113	Mild and moderate Gingivitis	Adults	A double blind, vehicle controlled monocentre clinical trial with parallel group design to demonstrate the efficacy and safety of Delmopinol in comparison to Chlorhexidine and Placebo	162	180 days
13	Elworthy et al. J Clin Periodontol	Gingivitis	Adults	A placebo-controlled, double blind	141	180 days

	1995;22:527-532			randomized unsupervised study to demonstrate the shift of plaque bacteria population.		
14	Claydon et al J Clin Periodontol 1996; 23:220-228	Effects on plaque, Gingivitis, supragingival calculus and toothstaining	Adults	Vehicle controlled double blind randomized unsupervised study to examine the efficacy of Decapinol mouthwash under unsupervised conditions	450	180 days
15	Francetti (Milan, Italy) et al. Poster Exhibited at FDI Stockholm 2008	Mild to Moderate Periodontitis	Adults	A double-blind, vehicle-controlled pilot clinical study to examine the efficacy and tolerability of MAS033 (Decapinol® gel) in the management of chronic Gingivitis and mild to moderate Periodontitis in adults	40	60 days
16	Klinge, Attstrom et al J Clin Periodontol 1996;23:542-547	Gingivitis	Adults	A double blind vehicle controlled study on 1.0% Delmopinol as represented in Decapinol Vials		
17	Dallessandri et. al. Poster, Congress of Italian Dentistry University Professors, Rome 2009	Mild to moderate Periodontitis. Remaining of Delmopinol in gum pockets	Adults	Delmopinol, injected via perio applicator remains detectable over 60min in the gum pockets	12	60min
18	Rumio, C. Poster FDI 2008	Comparison of different Toothpastes among plaque inhibiting activitu	Ex vivo	Decapinol toothpaste showed the most efficacious result in preventing plaque formation.	7 Artificial mouth models	
19	Zanotti et al. Poster FDI 2008 Stockholm	Comparison among plaque inhibiting compunds	Ex Vivo	Different plaque-inhibiting compounds were tested vs sterile water for their ability to reduce plaque formation.	6 Artificial mouth models	1 week



8.0 Regulatory Status

In the European Union, Decapinol® mouthwash and toothpaste are registered as a Class IIa medical device.

9.0 Sinclair Pharmaceuticals Ltd

As a leading skin and mouth disease specialist, we strive to improve the health, appearance and confidence of our patients, creating value for healthcare providers and shareholders.

Sinclair Pharma has a growing sales and marketing operation that is present in France, Italy, Germany and Spain, and an extensive marketing partner network across selected developed & emerging markets.

Sinclair Pharma plc is listed on the London Stock Exchange and Euronext Paris.

For further information please visit the website www.sinclairpharma.com

10.0 References

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