Study Synopsis

In situ mineral change and fluoride retention of sound and demineralized enamel in high cariogenic milieus following the single application of a 1.25%-fluoride or a placebo gel.

GABA Study Number: GASAS-0809X

EUDRACT Number: 2008-008594-58

Collaboration Centre:
Department of Operative Dentistry and Periodontology
School of Dentistry
University Hospital Freiburg
Hugstetter Straße 55
D-79106 Freiburg

Prof. Dr. Elmar Hellwig

Sponsor:
GABA International AG

Grabetsmattweg

CH-4106 Therwil

SYNOPSIS

Name of Sponsor / Company: GABA International AG	Individual Study Table Referring to Part of the Dossier	(For National Authority Use Only)
Name of Product: elmex gel (elmex gelée)	Volume:	
Name of Active Ingredient: Amine fluoride Olaflur 0,23 % F^- Amine fluoride Dectaflur 0,02 % F^- Sodium fluoride 1,00 % F^-	Page 51	

Title of the Study:

In situ mineral change and fluoride retention of sound and demineralized enamel in high cariogenic milieus following the single application of a 1.25%-fluoride or a placebo gel.

Investigators:

Prof. Dr. Elmar Hellwig

Dr. Markus Altenburger

Study Centre:

Department of Operative Dentistry and Periodontology

School of Dentistry

University Hospital Freiburg

Hugstetter Straße 55

D-79106 Freiburg

Publication (references):

Not published yet

Name of Sponsor / Company: GABA International AG	Individual Study Table Referring to Part of the Dossier Volume: Page 51	(For National Authority Use Only)
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Study period: Date of first enrolment: 23.9.2009 Date of last completed: 11.3.2010	Phase of Development: IV

Objectives:

Evaluation of the mineral change, change of the lesion depth and change of the fluoride content in sound and demineralized enamel specimens after a single tray application of elmex gel or placebo and subsequent high cariogenic conditions.

Methodology:

Transverse microradiography - TMR

Fluoride content measurement

Number of Subjects (planned and analyzed):

Planned 36, analyzed 38 safety analysis/ 36 efficacy analysis

Diagnosis and main criteria for inclusion:

Healthy subjects matching inclusion, not violating exclusion criteria.

Test product, dose and mode of administration, batch number:

elmex gel (elmex gelée), 7 g, intraoral tray application, topical on oral mucosa

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Name of Active Ingredient: Amine fluoride Olaflur 0,23 % F^- Amine fluoride Dectaflur 0,02 % F^- Sodium fluoride 1,00 % F^-		
Duration of treatment: 4 Minutes		
Reference therapy, dose and mode of administration, batch number: placebo gel , 7 g, , intraoral tray application, topical on oral mucosa		
Criteria for evaluation: **Efficacy:** Change of mineral content, change of lesion depth, change of fluoride content of sound and demineralized enamel specimens **Safety:** Recording and analysis of adverse events		
Statistical methods: Paired t-test		

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Summary – Conclusions:

Efficacy Results:

The treatment of sound enamel specimens with elmex gel prior to the exposition to high cariogenic condition led to a statistically significantly lower demineralization compared to sound specimens that were treated with a placebo gel ($p<0.001$). Also the lesion depth increased significantly lower in the elmex gel group compared to the placebo group ($p<0.001$). No statistically significant difference could be found after measuring the fluoride content. In both groups higher fluoride levels were measured but these were not statistically significant.

The application of elmex gel on demineralized enamel specimens prior to an exposition to a high cariogenic environment led to a deposition of minerals in the lesion, whereas treatment with placebo led to further demineralization. The same effect was observed for the lesion depth. Treatment with elmex gel decreases, treatment with the placebo gel increases the lesion size. Both analyzed parameters are statistically significant different from each other.

In both groups, , the treatment with elmex gel or placebo gel led to a higher fluoride content in sound and demineralized enamel. However these values were not statistically significant from each other.

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Safety Results:

18 adverse events (AE) were observed of which three cases were classified as 'definite' in relation to a possible causality of its occurrence and the study product. The symptoms of these three adverse events were 'burning feeling' in the oral cavity and ablation of the oral mucosa.

No serious adverse event (SAE) was observed.

Conclusion:

With the present results it can be concluded that elmex gelée induces a remineralization of demineralized enamel or at least hampers demineralization of enamel even under high cariogenic conditions. It can be recommended for caries prevention in 'high risk groups'. The observed adverse symptoms have already been described in literature and must be taken into consideration when this product is applied.

Date of report: 17.11.2011