VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Recent events of the human influenza (H1N1 virus) pandemic have exposed a central role for sore throat in the basic clinical presentation of the disease[12]. 'Acute sore throat' is a term often used to describe pharyngitis, tonsillitis and laryngitis that occur for a short period of time. On average, regardless of a pandemic influenza year, an adult may experience 2–3 sore throats over a period of 12 months, whereas children are more susceptible and are likely to experience more sore throat episodes[13], because of their immune naivety.The symptoms of sore throat vary between individuals and include a local mild discomfort with a scratchy-like sensation, swelling, pain with a 'raw' sensation and difficulty in swallowing. Most cases of acute sore throat due to URTIs, caused by a range of viruses, are generally not serious and are self-limiting, usually improving within 1 week[14].

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[12] *Writing Committee of the WHO Consultation on Clinical Aspects of Pandemic (H1N1) 2009 Influenza, Bautista E, Chotpitayasunondh T, Gao Z, et al. Clinical aspects of pandemic 2009 influenza A (H1N1) virus infection. N Engl J Med 2010;* ***362****: 1708–19.*

[13] *Marshall S: Giving advice on sore throats. Pharm J 2008; 280: 127–30.*

[14] *Oxford JS, Leuwer M. Acute sore throat revisited: clinical and experimental evidence for the efficacy of over-the counter AMC/DCBA throat lozenges. Int J Clin Pract. 2011 May; 65(5):524-30.*

VI.2.2 Summary of treatment benefits

Compared with oral analgesic treatments, topical remedies such as throat lozenges, gargles and throat sprays, which are applied directly to the mucous membranes of the mouth or throat, can provide more rapid symptomatic relief in patients with acute sore throat[14]. A study was designed to determine the analgesic properties of amylmetacresol and 2,4-dichlorobenzyl alcohol (AMC ⁄ DCBA) throat lozenges (Strepsils ®_) in the relief of acute sore throat caused by URTIs. This study clearly demonstrates significant analgesic effects and improvements in functional impairment scores with the use of amylmetacresol and 2,4- dichlorobenzyl alcohol throat lozenges (Strepsils ®), over and above the demulcent effects of nonmedicated lozenges, thus rendering these lozenges as a valuable treatment option in the self-management of acute sore throat. The conclusions of this study were that Amylmetacresol ⁄ DCBA throat lozenges provide rapid analgesic effects that last for 2 h, providing ongoing relief long after the lozenge has dissolved. The superior analgesic effects and improvements in functional impairment scores observed with AMC ⁄ DCBA throat lozenges translate into pain relief benefits that are clinically meaningful and are thus a suitable OTC treatment option for patients in the self-management of acute sore throat[6] .

One randomised double blind placebo-controlled trial was carried out evaluating the efficacy and tolerability of lidocaine 8 mg lozenges in 160 subjects with moderate to severe (> 60 mm on a visual analogue scale (VAS) for less than 72 hours) pharyngeal pain due to an acute (non-bacterial) pharyngitis. A maximum of six lozenges was allowed over a period of 24 hours with a dose interval of 2 hours. The primary endpoints were the AUC of Pain Intensity over 0-2 hours after administration and the VAS for pain relief after the last lozenge was sucked before returning to the clinician for 48-hours. Results with respect to the secondary endpoints (onset of 'meaningful' and 'complete' pain relief, number of subjects discontinuing due to lack of efficacy, global assessment of efficacy by subject and the number of tablets administered) confirm the results for the primary endpoint[15].

An additional single centre, randomised, double-blind, placebo-controlled parallel group study was conducted in 240 patients with an acute sore throat not requiring treatment with antibiotics. The study covered a treatment phase of 2 days and was divided into 2 phases: 2-hour laboratory phase and a 2-day out-patient phase. Efficacy data demonstrated statistically significant differences between lidocaine 8 mg lozenges and placebo: pain intensity reduction was after 2 hours 24% (from 73.1 mm to 55.5 mm) in the active group and 13% (from 73.6 mm to 63.9 mm) in the placebo group; after 48 hours these percentages were 45% (28.5 mm) and 30%, (44.1mm) respectively. These data were further supported by secondary outcome measures such

[15] *Public Assessment report of the Medicines Evaluation Board in the Netherlands (MEB). Trachisan 8 mg, lozenges, lidocaine (as hydrochloride monohydrate). Engelhard Arzneimittel GMBH & Co. KG, Germany. 29 March 2009.*

as the percentage of patients with meaningful pain relief defined as 50% reduction in pain score. The proportion of subjects with meaningful pain relief at 2 hours was 38% and 12% for lidocain and placebo respectively. Onset of meaningful pain relief was 0.4 hours for the lidocaine and 0.7 hours for placebo. This study confirmed the results of the previously submitted placebo controlled study[15].

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VI.2.3 Unknowns relating to treatment benefits

Not applicable

VI.2.4 Summary of safety concern

Table 11. Summary table of safety concerns for public summary

Important identified risks

Risk	What is known	Preventability
Hypersensitivity (eg. rash, urticaria, pruritus, mouth or pharyngeal oedema)	Due to the sensitivity to the active substances or any of its excipients this product can cause hypersensitivity reactions (burning, itching), angioedema, stinging of the throat and unpleasant taste.	The patient should be aware about all the ingredients in the lozenges formulation and avoid their consumption in case previous history of hypersensitivity to any of them is known.
Pulmonary aspiration	The anaesthesia caused by this drug in the throat area may enhance aspiration (coughing during meals or a choking sensation) while eating.	The patient should be aware that the production of topical anesthesia may impair swallowing and thus enhance the danger of aspiration. For this reason, food should not be ingested directly following use of local anesthetic preparations in the mouth or throat area.
Impact on nervous system: convulsions, cardiac effects (when taken in large amounts or repeatedly)	Follow the indicated dosage: when taken in large amounts or repeatedly, this medicine may impact the nervous system as it passes	The patient should follow the indicated dosage.

Risk	What is known	Preventability
	through the bloodstream, possibly causing convulsions or affecting the heart.	

Missing information

Risk	What is known
Use in paediatric patients < 12 years	Due to its lidocaine content which can lead to toxicity (neuro and cardiotoxicity), this product is not recommended for children under 12 years old.
Use in pregnancy and lactation	There is no sufficient information regarding the use in pregnancy and lactation: Pregnancy: In the absence of documented experience, the use of the product is not recommended during pregnancy. Lactation: A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from this medicinal product therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

VI.2.5 Summary of additional risk minimisation measures by safety concern
Not applicable

VI.2.6 Planned post authorisation development plan
Not applicable

VI.2.7 Summary of changes to risk management plan over time
Not applicable