A Review of the Efficacy and Safety of Nasaleze™ in the Prevention and Management of Allergic Rhinitis

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Abstract: Nasaleze™ is an inert cellulose powder which has been on sale in the UK since 1994 and is used as a remedy for hay fever. It is applied to the nasal passage where it forms a gelatinous coating, thereby trapping aero-allergens and preventing the initial allergic response. Some limited clinical studies have been conducted in predominantly adults but also in children: outcome measures included the reporting of symptoms by volunteers (sneezing, itching, blocked nose, etc) using questionnaires; prevention of symptoms when challenged to aerosolized allergens; concomitant use of rescue medication and the measurement of inspiratory air flow across the mucosa as well as the release of ECP in nasal washings. The product has been reported to be safe and well tolerated by all volunteers and warrant further investigation in larger studies.

INTRODUCTION

Seasonal and/or perennial allergic rhinitis is on the increase world wide, having increased two- or three fold over the last 15 years and current prevalence studies indicate that almost 15 million individuals are affected in the UK and 50-60 million people having been diagnosed in the USA alone [1]. It is often left undiagnosed due to the heterogeneity of the presenting symptoms, notably sneezing, itching, nasal congestion and very often, rhinorrhoea. Rhinitis is possibly one of the most debilitating conditions for sufferers due to the fact that the symptoms are often so severe that medications used during such crises are not fast-acting enough to provide relief and almost always induce side-effects which prevent the users from participating in normal day-to-day activities.

Nasaleze™, is an inert, micronized cellulose powder delivered in a patented delivery system. This proprietary grade powder is registered since 1994 and is currently on sale in many countries, including the UK. It is applied to the nasal mucosa where it forms a gelatinous coating, thereby preventing the airborne allergens from triggering the release of vasoactive substances from the mast cells lining the mucosa. It can therefore be considered not only as an effective measure to prevent the initial immunological reaction but also as a management strategy for reducing the symptoms of the allergic rhinitis once triggered.

This product has recently been commercialized in South Africa and is sold mostly through health store outlets or though some prescribing clinicians. It is relatively unknown although it has been available in the UK and some European countries. A mini-review of its properties and clinical benefits was therefore necessitated and this is presented herein: no other reviews of this product have been previously conducted.

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METHODS

A computerized literature search using the National Library of Medicine's Medline database and ScienceDirect journal access was conducted and any relevant articles referring to the product was extracted. Key words used for the search included: rhinitis & cellulose powder, Nasaleze, allergen challenge & powder, inert powder & rhinitis. This search yielded 5 published papers [2-6] and 4 poster presentations at congresses. They all referred to the work conducted using Nasaleze™, the product containing an inert cellulose powder. The congress poster presentations were often abstracts of the full articles and for this reason, they were excluded from this analysis: only the data of the published literature were extracted and is presented under the following categories:

a. Study designs and patient population studied

b. Study outcome measures, safety and product acceptability

c. Possibilities of product development

This review is no attempt to represent a meta-analysis of the published data since the literature is too limited and the study outcomes are too varied to conduct such an analysis.

RESULTS

A. Study Designs and Patient Populations Studied

Most of the published works deal with patients recruited by means of advertisements placed in national and local press media. The patients were required to complete pretrial questionnaires which pre-selected the patients based on predefined criteria for eligibility such as range of rhinitis symptoms, severity (requiring medication for management), time of the year when symptoms were at their worst, etc. The self-reporting questionnaire graded the patients on a point scale

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system (1 for severe uncontrolled symptoms to 5 for an indication of well-being, no symptoms): changes in any of the scores could be used to determine the eventual outcome of the interventional study.

In some studies, recruited patients participating in the study had recourse to rescue medication and this was recorded in daily journals since the use of concomitant medication was an indirect measurement of the efficacy of the Nasaleze™ product in the control of the patients' symptoms. In other studies, a new formulation (Nasaleze™ Travel) was compared to the routine preparation in the prevention of airborne infections which could have been acquired whilst traveling. Yet another study challenged volunteers to house-dust mite allergens and determined the efficacy of the Nasaleze™ product in preventing the allergic reaction. The studies are summarized hereunder in Table **1**.

All of the above studies made use of selected patient population either recruited *via* the general practitioners who referred their patients to the study sites or volunteers who responded to recruitment advertisements *via* the local press. The respondents were screened for participation in the studies and the criteria used included severity of symptoms based on allergy medication history, seasonality of symptoms (pollen counts also used to determine whether the symptoms corresponded to high allergenic challenge), accessibility for follow up, etc. In most studies, compliance was never compromised and fall out from the study was minimal since most volunteers benefited from the intervention. This in itself was an indication of the efficacy of the product in controlling the symptoms. The intervention periods were relatively short (4-8 weeks) and yet, efficacy outcomes were achieved and these were reported by the authors.

Although questionnaires were used to determine study outcomes (these could be considered as biased tools to measure efficacy), some studies made use of biomarkers which provided unbiased, quantitative laboratory data to corroborate the clinical outcome measures. These are reported in the following section.

B. Study Outcome Measures, Safety and Product Acceptability

The studies made use of questionnaires which was scored by the volunteers and these recorded their sense of wellbeing. Some limited laboratory biomarkers of successful intervention were also recorded in some studies. Furthermore, accessibility to rescue medication during some of the studies was considered as an unbiased measurement of the ability of the product being investigated to manage the symptoms of the patients. These results are summarized hereunder (Table **2**).

All of the studies clearly showed efficacy of the cellulose powder in reducing symptoms associated with either seasonal or chronic rhinitis without the need of the patient to make use of pharmaceutical drugs (although very few patients had such recourse). The most significant findings are that the product is well tolerated, safe and easy to apply. The independent measurements of efficacy included measurements of improved inspiration and expiration air flow implying that the use of the product lead to less inflammation and oedema at the mucosal surfaces. The use of the inert powder by children (and possibly pregnant women) is an added advantage: not many drugs can be used by these target populations without medical advice and warning.

The lack of significant difference in the symptoms scores between the placebo and active group in the study by Emberlin & Lewis [4] deserves some discussion: the authors reported that at the 1% significance level, no differences existed between the groups. However, at the 5% level, differences were reported by the volunteers for some symptoms such as "running nose" or "blocked nose" and this tended to correspond to days with lower pollen count days. However, these significant differences were lost when the total Likert score was compared between the groups.

C. Possibilities of Product Development

The study conducted using the cellulose powder as a carrier of bioactive molecules, in this case, an extract of garlic,

Table 1. Summary of Published Studies Making Use of Nasaleze™

Authors	Number of Patients Recruited	Patient Population	Type of Study	Duration of Study Period
Josling & Steadman (2003)	102 (66 females, 36 males).	Adults (mean age = 44 yrs): reporting seasonal rhinitis.	Open labeled: volunteers compared present product to previously used drugs.	6 weeks.
Aivazis W *et al.* (2005)	100 (47 girls, 53 boys).	Children (age range 1.5 – 18 years, mean age = 7.96 years).	Open labeled: measurement of mucocilliary clearance in allergic rhinitis pre- and post therapy with Nasaleze™	6 weeks.
Emberlin & Lewis (2006)	97 (57 females, 40 males).	Adults (mean age = not reported): hay fever sufferers.	Randomised, double blind, placebo-controlled. Patients recorded symptoms including Likert scores. Rescue medication permitted.	4 weeks.
Emberlin & Lewis (2007)	15 (7 females, 8 males).	Adults (modal age range 38-47 yrs): selected specifically for house dust mite allergy.	Double blind, cross over challenge study using Der p1 and Der f1 sensitivity.	1 month recruitment and 2 week actual study at clinic.
Hiltunen *et al.* (2007)	52 (gender distribution not stated)	Adults (mean ages not reported).	Randomised, double-blind study of Nasaleze™ vs Nasaleze™ Travel (with garlic extract) to determine prevention of airborne infections.	8 weeks.

Table 2. Outcomes, safety and Product Acceptability

Study	Significant Findings	Compliance and Safety	Conclusions Drawn by Authors
Josling & Steadman (2003):	77% of volunteers reported success (either good or excellent) by end of 6 weeks; average scores of 3.8 by men and 3.9 by women (5 indicating symptom free) were achieved: this was better when compared to pharmaceutical drugs used in the past; symptoms controlled within 0.1 – 3 hours after use.	No major problem: some volunteers reported some discomfort in throat due to powder. Only 8 patients required additional treatments.	Pilot study which clearly indicated that further investigations were warranted. Inert powder not medicated hence no side-effects with added advantage. Product well tolerated and provided fast relief.
Aivazis *et al.* (2005):	Only study conducted in children: statistically significant improvement in mucociliary clearance (39 mins. to 18.15 mins and this was directly related to improved peak nasal inspiratory flow rate (114.9 L/min to 144.4 L/min) implying less oedema and inflammation following use of product.	Excellent tolerance to product: no safety issues raised by volunteers.	The results imply the regeneration of ciliary epithelium. Product can be used by children.
Emberlin & Lewis (2006):	Blinded study in hay fever sufferers with significant differences in outcomes between groups: placebo used more rescue medication ($p < 0.05$) although Likert scores showed no differences.	No adverse effects reported during trial: both powders well tolerated. The placebo powder (lactose) may have provided some protection to the users.	The inert cellulose powder provides safe and effective protection thereby obviating the need for anti-histamine and other pharmaceutical drugs for the symptoms.
Emberlin & Lewis (2007)	Allergen challenge in house dust mite allergic individuals: significant decrease in biomarker ECP ($p < 0.05$) in nasal secretions as well as significant increase in measurements of nasal air flow ($p < 0.05$) when placebos compared to active. Cross over period of study proves efficacy of cellulose powder in preventing allergic reaction.	No adverse effects reported by any volunteer.	Nasaleze™ has ability to significantly reduce symptoms of persistent rhinitis due to house dust mite and possibly provides effective barrier to inhaled allergens.
Hiltunen *et al.* (2007):	Significantly less infections (all combined) reported by volunteers using powder enriched with garlic extract compared to users of powder alone ($p < 0.001$) and days affected by airborne pathogens also different between groups (less days reported ill, $p < 0.05$).	Volunteers continued with their daily travel plans and this study (albeit small) shows that garlic extract enriched cellulose powder provided effective barrier to airborne pathogens. No adverse effects reported by volunteers.	Cellulose powder can be used as effective carrier of bioactive molecules to prevent airborne pathogens during traveling.

presents exciting novel applications of the technology to address other important medical challenges. This trial showed that the active could be absorbed *via* a well vascularized mucosa and provide the efficacy sought (prevention of airborne infections). Numerous studies are currently searching for ways to deliver small amounts of antigenic peptides for immunization purposes since the immune cells of these surfaces are extremely powerful antigen presenting cells and are thus able to induce an immune response in the draining lymphoid organs. Also, the delivery of other natural molecules which have been described as effective anti-inflammatory compounds [7] for the management of chronic conditions affecting the mucosal surfaces is another area of research which warrants investigation by the manufacturers of the product.

CONCLUSIONS

The treatment of allergic rhinitis to date has relied heavily on drugs that act either as membrane stabilizers thereby preventing the degranulation of the immune cells lining the nasal mucosae and which contain vasoactive peptides (steroid based drugs) or on drugs that neutralize the release of histamines (generic anti-histamines). Most of these drugs are not without side effects: they cause drowsiness and cannot be used by pregnant women. The novel product Nasaleze™ represents a new management strategy in the control and management of allergic rhinitis: this inert cellulose powder is administered into the nasal passages and forms an impervious barrier to the aero-allergens to which the individual may be sensitized. It is a natural and safe product, does not contain any drugs and above-all, has shown itself to be effective under trial conditions (albeit small studies).

The powder was tested not only as a preventative approach to attacks of hay fever but also as a treatment to the symptoms of allergic reactions, it stops the sneezing within minutes (response within 0.3 hours) and allows the improvement of air flow into and out of the nasal passages, thereby implying that it decreases the degree of on-going inflammation and oedema which normally accompanies an allergic reaction. These findings were corroborated by the laboratory measurement of decreases in the nasal washings of released ECP (Eosinophilic Cationic Protein), a biomarker of cellular degranulation.

The use of the inert powder as a carrier medium for bioactive molecules such as garlic extract to prevent travel-associated infections showed interesting results: fewer infections were reported by the volunteers who applied this enriched powder during their travels locally and even internationally. The study however is not clearly defined due to the fact that some patients traveled internationally using air

travel while others may have been using local train travel. The study implies that other molecules could be tested using this safe carrier. Further studies using larger patient groups are certainly warranted and these should include other immune biomarkers of efficacy, such as IgE levels, specific IgE titers to offending allergens, etc.

DISCLOSURE

The author would hereby like to declare that he has no vested interest (financial or otherwise) in the product being reviewed in this article. The need for such a review was necessitated by the fact that the product was unknown at the time of its launch in South Africa.

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Nasaleze 用于预防和治疗过敏性鼻炎的有效性和安全性的综述

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摘要：Nasaleze 是自 1994 年就在英国上市的惰性纤维素粉末，被用作枯草热疗法。用于鼻道，形成凝胶样涂层，从而圈住气源性过敏原并防止最初的过敏性反应。主要在成人，也有在儿童开展了一些有限的临床研究 结果测量包括采用调查问卷志愿者自报症状（喷嚏、痒、鼻塞等）；雾化吸入性过敏原激发症状的预防；急救药物的伴随使用、整个粘膜的吸气流量测定和鼻冲洗液中 ECP 的释放。所有志愿者都称该产品很安全并耐受性良好，并保证将在更大规模的研究中作进一步研究。

简介

季节性和/或常年性过敏性鼻炎在世界范围内增长，在过去 15 年内增加了两至三倍，目前的患病率研究显示英国几乎 1500 万人患有过敏性鼻炎，仅美国就有 6000 万人诊断有过敏性鼻炎。由于症状的异质性，特别是喷嚏、鼻痒、鼻塞和经常出现的鼻漏，常常未能诊断。鼻炎很可能是患者最衰竭性疾病之一，因为症状常很严重而这种情况下药物并不能够快速起作用缓解这些症状，并且几乎总是引起副作用，使使用者不能参加正常的日常活动。

Nasaleze 是采用专利输送系统的惰性微粉化纤维素粉末。专有等级粉末自 1994 年注册，目前在包括英国的许多国家销售。用于鼻腔粘膜形成凝胶样涂层，从而防止气源性过敏原诱发血管活性物质从粘膜内的肥大细胞释放。因此可认为不仅是防止最初免疫反应的有效措施，也是减少一旦诱发的过敏性鼻炎的治疗策略。

该产品最近在南非上市，最主要是通过卫生保健商店网点或通过一些开处方医师销售。尽管其在英国和一些欧洲国家有销售，但在南非还不为人熟知。因此有必要对它的特点和临床效果做个小型综述，在此呈现：之前并没有其他有关该产品的综述。

方法

采用美国国立医学图书馆 NLM 的 Medline 数据库和 ScienceDirect 杂志访问进行计算机化文献搜索，提取任何提到本产品的相关文章。用于搜索的关键词包括：鼻炎&纤维素粉末、Nasaleze、过敏原激发试验&粉末、惰性粉末&鼻炎。该搜索找到 5 篇发表的论文和 4 篇大会的壁报。他们都提到采用 Nasaleze，该产品含惰性纤维素粉末。大会壁报常是全文的摘要，因此该分析排除了这些壁报：仅提取了发表的文献的数据，分成下面类别：

a. 研究设计和研究患者总体

b. 研究结果测量、安全性和产品可接受性

c. 产品发展的可能性

本综述不是要对发表的数据进行荟萃分析，因为文献太有限了。研究结果差异太大不宜进行这种分析。

结果

A． 研究设计和研究患者样本

大多数发表的文章的患者是通过在国家和地方新闻媒体放广告招募的。患者要求完成实验前调查问卷，根据此问卷预选定的患者预确定入选的标准，如鼻炎症状范围、严重程度（要求用药治疗）、症状最差时在一年中的时间等。自报的问卷按分数量表把患者分级（从 1 严重的未控制症状到 5 无症状的健康状态）:任何分数的变化可用于确定干预研究的最终结果。

一些研究中参与研究的招募患者借助于抢救药，这个在日志有记录，因为伴随用药的使用是 Nasaleze 产品控制患者症状的疗效的一个间接测定。其他研究，把新的配方（Nasaleze Travel）和在旅行中用到的用于预防气传感染的常规制剂进行了比较。尽管另一个研究用尘螨过敏原激发志愿者并测定 Nasaleze 产品预防过敏性反应的疗效。这些研究总结在下面的表 1 中。

表 1 使用 Nasaleze 的发表的研究的总结

作者	患者试验数	患者人群	研究类型	研究持续时间
Josling & Steadman（2003）	102（66 女，36 男）	成人（平均 44 岁）：自报季节性鼻炎	开放式 :志愿者目前用产品与之前使用药物比较	6 周
Aivazis W 等（2005）	100（47 女，53 男）	儿童（年龄范围 1.5-18 岁，平均 7.96 岁）	开放式：Nasaleze 治疗前后过敏性鼻炎的粘液纤毛清除功能的测定	6 周
Emberlin & Lewis（2006）	97（57 女，40 男）	成人（平均年龄没有报告）：枯草热患者	随机双盲安慰剂对照。患者记录症状包括 Likert 评分。允许的急救用药。	4 周
Emberlin & Lewis（2007）	15（7 女，8 男）	成人（年龄范围 38-47 岁）：特异性选择为尘螨过敏。	采用 Der p1 和 Der f1 敏感性的双盲交叉激发研究。	1 个月的招募期和 2 周的诊所确切治疗期
Hiltunen 等（2007）	52（男女分布未载明）	成人（平均年龄没有报告）	Nasaleze 与 Nasaleze Travel（大蒜提取物）的随机、双盲研究确定空气传播感染的预防。	8 周

上述所有研究使用了选择性患者总体，或通过全科医师招募，由全科医师推荐给研究点，或通过当地新闻志愿者响应招募广告慕名而来。响应者被筛选参加这些研究，采用的标准包括根据过敏药物病史判断的症状的严重性、症状的季节性（花粉计数也用于确定症状是否与高过敏原激发符合）、随访的可达性等。大多数研究，没有放弃依从性，研究退出最小，因为大多数志愿者从干预中获益。这个本身就是产品控制症状的疗效指征之一。干预期相对较短（4-8 周），但达到了疗效结果，这些可见于各作者的报道。

尽管调查问卷用于确定研究结果（这些可以作为测量疗效的偏倚工具），一些研究利用能提供无偏倚定量实验数据的生物标志物来确证临床结果测定。这些将在下节报道。

B．研究结果测量、安全性和产品可接受性

这些研究采用志愿者评分的调查问卷，这些记录了他们的幸福感觉。某些有限的成功干

预的实验生物标志物在某些研究也有记录。此外，一些研究中抢救药的可达性作为调查产品管理患者症状的能力的无偏倚测量。这些结果总结见下（表 2）。

表 2 结果、安全性和产品的接受程度

研究	重大发现	顺应性和安全性	作者的结论
Josling & Steadman（2003）	6 周末 77%的志愿者成功（好或大好）；男平均评分 3.8，女平均评分 3.9（5 分表示没有症状）：与过去用药相比结果更好；症状在使用后 0.1-3 小时内得到控制。	没有大的问题：一些志愿者报告因为粉末 喉咙一些不适。仅有 8 名志愿者要求额外的治疗。	试验研究清楚显示必须进一步研究。惰性粉末不是药，因此没有额外的副作用。产品耐受性良好，可快速缓解症状。
Aivazis W 等（2005）	仅是儿童研究：粘液纤毛清除功能统计显著提高（39 分钟提高到 18.15 分钟），这和鼻峰吸气流量改善（114.9L/min 增加到 144.4L/min）直接有关，提示产品使用后水肿和炎症减少。	产品有很好的耐受性：志愿者没有提出安全性问题。	本结果意味着纤毛细胞的再生。该产品可用于儿童。
Emberlin & Lewis（2006）	枯草热患者的盲研究显示组间结果有显著差异：安慰剂使用组使用更多的急救药($p<0.05$)，尽管 Likert 积分没有差异。	试验中没有报告副作用：两种粉末的耐受性都好。安慰剂粉末（乳糖）可对患者提供一些保护。	惰性纤维素粉末提供安全有效保护，因此可避免用于控制症状的抗组胺药和其他药品的需要。
Emberlin & Lewis（2007）	尘螨过敏个体过敏原激发：治疗组与安慰剂组比较鼻分泌物中生物标志物 ECP 显著降低（$p<0.05$），鼻空气流测定显著增加（$p<0.05$）。研究交叉期证实了纤维素粉末预防过敏性反应的疗效。	没人报告任何副作用	Nasaleze 可显著减少尘螨引起持续性鼻炎的症状，可能提供针对吸入性过敏原的有效屏障。
Hiltunen 等（2007）	使用富含大蒜提取物的粉末的志愿者比光用粉报告显著少的感染(综合所有) ($p<0.001$)，两组间空气传播病原体感染的日子也不同（生病日数少，$p<0.05$）。	志愿者持续其日常旅行计划，本研究（尽管小）显示富含大蒜粉末的纤维素粉末可提供针对空气传播的病原体。志愿者没有报告副作用。	纤维素粉末可用作生物活性分子有效的载体预防旅行中的空气传播病原体。

所有研究清楚显示了纤维素粉末在患者不使用药物时（尽管有很少很少的患者有借助药物）减少季节性或慢性鼻炎有关症状的疗效。最显著的发现就是该产品可以很好耐受、安全、易使用。疗效的独立测量包括改善吸气或呼气流量的测定，提示该产品的使用会减少粘膜表面的炎症和水肿。惰性粉末用于儿童（甚至还有孕妇）有个额外的优点：这个靶人群在没有医疗建议和警告，很多药不能用。

Emberlin&Lewis 的研究中安慰剂组和治疗组间症状评分没有显著差异值得一些讨论：作者报道在 1%的显著水平，两组间无差异。但是在 5%的显著水平，志愿者报告有某些症状如流鼻涕或鼻塞有显著差异，这和花粉计数低的日子符合。但是当两组间进行总 Likert 评分比较时，这些显著差异就没有了。

C． 产品发展的可能性

采用纤维素粉末作为生物活性分子—大蒜提取物的载体进行的研究显示了该技术解决其他重要的医学挑战的令人兴奋的全新应用。该试验表明，该活性可通过血管丰富的粘膜吸收，提供疗效（预防空气传播感染）。目前大量研究是寻找输送少量的抗原肽用于免疫的方法，因为这些表面的免疫细胞是非常强的抗原提呈细胞，因此可以在引流到的淋巴器官诱导免疫应答。同样，已经描述过的用于治疗累及粘膜表面的慢性疾病的其他天然分子的输送是研究的另一个领域，这由产品的制造商保证研究。

结论

过敏性鼻炎的治疗迄今为止已经严重依赖于药物，要么是防止鼻粘膜内的含血管活性肽的免疫细胞脱颗粒的膜稳定剂（以激素为基础的药），或者中和组胺释放的药（通用抗组胺药）。大多数药物不是没有副作用：这些药会引起嗜睡，孕妇不能用。新产品 Nasaleze 代表了控制和治疗过敏性鼻炎的新治疗策略：该惰性纤维素粉末进入鼻道，形成对患者可能过敏的气传过敏原的不透屏障。它是天然安全产品，不含任何药物，上述所有研究显示在试验条件（虽然是小研究）下其本身有效。

该粉末不仅作为枯草热发作的预防方法试验，也作为过敏反应的症状的治疗，它可在几分钟内（0.3 小时内反应）终止喷嚏，改善出入鼻道的空气流，因此这意味着它减少了持续炎症和水肿的程度，过敏性反应往往伴随有持续性炎症和水肿。这些发现被鼻冲洗液中 ECP（嗜酸性阳离子蛋白）降低的实验室测定证实了，ECP 是细胞脱颗粒的生物标志物。

惰性纤维素粉末作为生物活性物质如大蒜提取物的载体防止旅行相关感染的使用显示了有趣的结果：在国内甚至国外旅行中使用该含大蒜的粉末的志愿者鲜有报告感染的。不过本研究还没有明确，因为一些患者国外旅行是空中旅行，而其他可能是乘坐当地火车旅行。本研究意味着可以采用本安全载体测试其他分子。一定要保证用较大患者群做进一步研究，这些研究应该包括疗效的其他免疫生物标志物，如总 IgE 水平，过敏原的 sIgE 滴度等。

揭秘

笔者在此想声明他并没有从本篇文章回顾的产品获得利益。只是基于该产品在南非上市时没人知道它，有必要作个综述的需要。

参考文献

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