



## ADJUVANT THERAPY WITH TABLETS CONTAINING SODIUM JALURONATE, CARBOMER AND XANTAM GUM FOR GERD PHARYNGITIS

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### ABSTRACT

**Introduction:** Chronic pharyngitis is one of the most frequent diseases of the upper aerodigestive pathways. Gastro-esophageal reflux plays an important role in the genesis of this disease. In fact, the excessive exposure of the pharynx to the gastric contents leads to a chronic irritation of the upper airways.

On the basis of the foregoing, the study of the present work aims to document the effect of pastilles composed of xanthan gum, sodium hyaluronate, mannitol, sodium hydrogen carbonate, sorbitol, citric acid, aspartame, vitamin C, aroma, zinc citrate dihydrate. variation of salivary pH, of the symptomatology and of the objective picture in subjects affected by secondary interest in acidity of the oral cavity.

**Materials and methods:** 50 subjects were recruited. They were enrolled by the affiliated users to three ENT centers and supported by a gastroenterologist (Naples), 50 (25 males and 25 females) with average age of 37aa, Min 6 aa, Max 65 aa patients affected by secondary to acidity of the oral cavity. For each patient an objective examination was performed and then the salivary pH changes were evaluated, using indicator maps, and furthermore, the Reflux Symptoms Index (RSI) and Reflux Finding Scores (RFS) were administered before, during and after therapy to monitor the subjectivity of the symptomatology and the laryngeal objective picture.

**Results:** The survey performed allowed to establish a clear improvement in all phases of the study, both as regards the effects on pH, both on the side of the symptomatology and on the laryngeal objective.

**Discussion:** The motivation for improving the clinical condition of the subjects is due to the therapeutic properties of the substances used. In particular: the hyaluronic acid has a regenerating power of the mucosa; carbomer and Xanthana Gum have a viscoelastic behavior and contribute to the potency of ac. High molecular weight hyaluronic acid through the formation of a hydrocomplex of high tolerability mucoadhesive polymers.

**Conclusions:** Undoubtedly it is a product capable of restoring the physiological conditions of the oral cavity and the very first airways and their use not only acts as a restoration of the physiological conditions of the oral cavity, but also as a preventive action for the appearance of local and systemic diseases

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### INTRODUCTION

Chronic pharyngitis is one of the most common disease of the aereodygestive tract. The causes are different and among these, gastro-esophageal reflux plays an important role in the genesis of this disease.

The reflux inflammation is mainly caused by the excessive exposure of this anatomical area to the gastric contents, due to the dysfunction of various protective mechanisms that prevent reflux into the esophagus and a decrease in the natural resistance against reflux (1). Surely acidity of gastric contents plays the most important role in the pathogenesis of reflux damage and it is well known that intraluminal pH control plays a very important role in the management of this disease (2). In fact, some studies have documented how gastric reflux affects the acidity of the rhinopharyngeal district (3,4), and how it acts

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on its mucosa (5). In addition, other studies have documented the possibility of performing a semi-quantitative staging of pharyngeal inflammation (6). The aim of this study is to document the effect of pills composed of xanthan gum, sodium hyaluronate, mannitol, sodium hydrogen carbonate, sorbitol, citric acid, aspartame, vitamin C, flavoring, zinc citrate dihydrate on the variation of salivary pH, of the symptomatology and of the objective picture in subjects affected by secondary interest in acidity of the oral cavity

**MATERIALS AND METHODS**

In this study the relationship of salivary pH variation, determined by means of indicator maps, was evaluated in subjects affected by secondary acidity of the oral cavity, before and after intake of tablets composed of xanthan gum, sodium hyaluronate, mannitol, sodium hydrogen carbonate, sorbitol, citric acid, aspartame, vitamin C, flavoring, zinc citrate dihydrate. They were enrolled by the users belonging to three otorhinolaryngoiatric centers and supported by a gastroenterologist (Naples), 50 (25 males and 25 females) with an average age of 37aa, Min 6 aa, Max 65 aa patients suffering from secondary interest in acidity of the cord oral. The inclusion and exclusion criteria are shown in Table 1

**TAB 1** inclusion (sin) and exclusion criteria (dx).

Inclusion criteria	Exclusion criteria
Anamnesis or diagnosis of GERD	Oncological disease
Not Pharmacological treatment with antibiotics, cortisone, PPI, antihistamines cromolyn, anti reflux drugs or prokinetics,gative anamnesis for allergy	Pharmacological treatment with antibiotics, cortisone, PPI, antihistamines cromolyn, anti reflux drugs or prokinetics,
Absence of significant malformations of the nasal cavities	significant malformations of the nasal cavities
Exclusion of dental diseases	Uncorrect dental hygiene
Exclusion of infectious diseases of the first ai	Infectious diseases of the first airways
Not smokers	Smokers
Negative allergy anamnesis	Allergy anamnesis
	Pregnancy

After completing the privacy process and informed consent, all patients underwent an objective examination, a 4-mm diameter Olympus rinofibroscopy was performed using disposable sheaths as a means of prevention; the anatomical elements of GERD have been identified, such as the presence of a generalized mucositis, oropharynx in the form of a geographical map and above all, at the level of the glottal plane, hyperemia of the interaridenoidea region. The next day they went to our clinic without having drunk or run the daily dental toilet to undergo the salivary test. For the determination of salivary pH from each patient, 2.5 ml of saliva were collected in a beaker, without any stimulation, having previously had the mouth washed with water, to avoid contaminants. A Macherey-Nagel strip of pH 1-14 was immersed in saliva and after a few seconds the color of the relative pH value was visualized. Evaluated more precisely by another PEHANON indicator map, with reduced interval. any variation in the pH of the two districts was evaluated, through the t-Student test. The significant reference was p <0.05. The investigation was performed before administration, twenty minutes later, twenty days later, and another twenty days. In addition, the Reflux Sympomps Index (RSI) (7)Tab 2 was administered, and the Reflux Finding Scores (RFS) (8)Tab 3 before, during and after therapy to monitor the subjectivity of

the symptomatology and the laryngeal target frame. The latter were used in the T2 and T3 times to allow the product to perform the therapeutic functions.

**Tab 2**

Dysphonia	1	2	3	4	5
Need to scrape the throath	1	2	3	4	5
Excess of mucus or postnasal drip	1	2	3	4	5
Dysphagia (solids, liquids)	1	2	3	4	5
Cough after meal or in supine position	1	2	3	4	5
Difficulty breathing	1	2	3	4	5
Severe cough	1	2	3	4	5
Foreign body feeling	1	2	3	4	5
Heartbum	1	2	3	4	5

**Tab 3**

Subglottic edema	2 +			
Obliteraziventricolar				
obliterationone	2 partial		4 complete	
ventricolare				
Hyperemia	2 aryteneoids		4 complete	
Vocal cord edema	1 slight	2 moderate	3 severe	4 polipoid
Edema diffuso	1 slight	2 moderate	3 severe	4 obstructive
laringeo				
Iperetrofia	1 slight	2 moderate	3 severe	4 obstructive
commissurale posteriore				
Granuloma	2 +			
Ispessimento mucoso	2 +			
endolaringeo				

**RESULTS**

The study carried out immediately documented a significant improvement in pH. In fact, the average calculated over time T1 has documented a significant variation in pH that has passed from an average observed at T0 4.46 (median 4, standard dev 0.54, minimum, 4, maximum 6) to 5.68 (median 6, standard deviation 0.71, minimum, 4, maximum 7). In this phase the 7 cases were observed the appearance of a physiological pH. (Tab. 4). In phase T2, the pH has undergone further improvement. The detected pH was 6.5 (median 7, standard dev 1.1, minimum, 5, maximum 8). During this period, the subjective RSI symptomatology had a response from the patients with a marked improvement compared to the T0 (mean median 11.92 11; standard deviation 2.39, minimum, 10, maximum 19). At this stage, the average was 7.58 (median 8, standard dev 1.23, minimum, 5, maximum 9).(Tab. 5). As well as the RFS had an improvement starting from T0 (mean 10.04 median 8, standard deviation 1.01, minimum, 8, maximum 18) at T2 the mean was 7.68 (median 10; Standard 0.71, minimum, 5, maximum 10). (tab6) At T3, the pH reaches an average physiological value in all the subjects examined. Only in one case has an alkaline value of 8 been reached (median 7 dev.

Standard 0.2, minimum, 6, maximum 8). (tab 4). The symptomatology (RSI) in the mean value (median 7 dev. Standard 1,23, minimum, 5, maximum 8)., Compared to the previous time, remained unchanged however in 13 patients, equal to 26% of the subjects examined, the value appeared in a tendency to improve. (tab 5) The objective examination (RFS), in this phase, was significantly improved with an average value of 6.66 (median 7 dev. Standard 0.84, minimum, 5, maximum 9). (Table 6)

## DISCUSSION

Salivary pH is determined for the maintenance of a natural microbial flora. Indeed, many microorganisms require a pH around neutrality for growth and are sensitive to extreme acidity or alkalinity. The pH of most of the surface of the mouth is regulated by saliva; The mean pH, studied under basal conditions, for the entire saliva is between 6.75 and 7.25, thus providing an optimal pH for physiological microbial growth. In cases of gastroesophageal reflux the pH of the oral cavity becomes acid (4), causing a series of pathologies of the same (9). In fact, it is part of the defenses of an adaptive and innate immune system. These often work synergistically and at very low concentrations, developing a complex relationship between the host and the resident microbiota. Thus, dysbiosis can occur quickly if the flow of saliva is altered by gastroesophageal reflux, even if it is small. In the cases observed, the pH variation was already evident in the first twenty minutes from the administration of the product. This picture has improved in the following times until a physiological pH is reached. On the other hand, the symptomatology of the subjects observed (RSI) reached an optimal condition already starting from T2 (at twenty days later), with the maintenance of this state up to the fortieth day (T3). This result allows us to detect that the patient has benefited from the beginning of the administration of the product. Regarding the objective frame (RFS) it can be deduced that it presents a constant improvement starting from T2 up to T3 and appears congruent with the evolution of the symptoms, given the difference between the two times. The results obtained with the use of the tablet composed of xanthan gum, sodium hyaluronate, mannitol, sodium hydrogen carbonate, sorbitol, citric acid, aspartame, vitamin C, flavoring, zinc citrate dihydrate. to restore the normal physiological conditions in the oral cavity to restore the normal microbial flora, thus avoiding the appearance of local (10) and systemic (11) clinical complications. The Therapeutic motivation is basically given by three factors:

High molecular weight Hyaluronic Acid which has been shown to regenerate the pharynx mucosa. (12)

Carbomer is a high molecular weight polymer of acrylic acid. It is a homopolymer and is only moderately cross-linked. Carbopol 71G NF has a relative molecular mass of about  $1.25 \times 10^6$ . They have fair mucoadhesive properties. Carbomer is a synthetic polymer rich in carboxyl groups, which increases in volume in an aqueous environment, assuming mucomimetic properties. Thickening and oral mucoadhesive. The mode of action of carbomer is based on purely physical processes (such as viscosity). Absorption of carbomer in the gastrointestinal tract is negligible. Carbopol as such would have an effect of reducing the surface of the wounds, probably due to its mucoadhesive properties. The carbomer would act as a wound cover, preventing contamination and irritation of the damaged tissue - an effect that would facilitate faster healing. After oral ingestion, carbomer is excreted in the faeces in an almost completely unchanged form. The carbomer formulations allow a sustained drug release over time. Mucoadhesion properties have been extensively studied and countless drug delivery systems have been developed. (13)

Xanthan gum is a high molecular weight natural polysaccharide obtained from fermentation processes. The relative molecular mass of xanthan gum is about  $1 \times 10^6$ . The

xanthan gum dissolves slowly, has a viscoelastic behavior and is subject to swelling in an aqueous environment (14). Its use is also optimal for the formation of buccal biofilms, due to its physico-chemical properties and to the lower erosion potential of the polymer matrix on the mucous membranes.

## CONCLUSIONS

The tablets made of xanthan gum, sodium hyaluronate, mannitol, sodium hydrogen carbonate, sorbitol, citric acid, aspartame, vitamin C, flavoring, zinc citrate dihydrate are undoubtedly a product capable of restoring the physiological conditions of the oral cavity and the very first airways, through mechanisms characterized by a set-up of a hydrocomplex of mucoadhesive polymers with high tolerability and safety, with viscoelastic properties, such as to guarantee a longer time of permanence of the therapeutic principles on the mucosa in order to maximize its effectiveness on inflamed mucous membranes. Their use not only acts as a restoration of the physiological conditions of the oral cavity, but also as a preventive action for the appearance of local and systemic diseases.

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