



KAROS[®] ORAL SPRAY
0.3% SODIUM HYALURONATE SOLUTION
FOR ORAL USE

PRODUCT CHARACTERISTICS

KAROS ORAL SPRAY is a hyaluronic acid-based solution to be sprayed into the throat in case of oropharyngeal mucosal inflammation (inflammation of the oral and pharyngeal mucosa).

Thanks to its particular viscoelastic and physical properties, hyaluronic acid forms a protective barrier on the inflamed oropharyngeal mucosa; in fact, being a hydrophilic molecule, it is able to absorb water up to 1000 times its volume, forming almost a gel.

For this reason, spraying hyaluronic acid-based KAROS ORAL SPRAY directly into the aqueous environment of the oropharyngeal area allows the formation of a thin film. This film acts as a protective barrier for the pharyngolaryngeal mucosa in case of mucosal inflammation caused by gastroesophageal nonerosive reflux disease (NERD) or diseases of the upper respiratory tract, such as pharyngitis and laryngitis, in both acute and chronic phases.

Reflux disease is significantly widespread, especially in the western world, and is closely related to lifestyle and dietary habits.

Reflux of stomach acid into the oral cavity, i.e. into the pharynx and larynx, is recognised within the category of gastroesophageal nonerosive reflux disease (NERD) and is defined as laryngopharyngeal reflux disease, often abbreviated as LPR.

In this disease the gastroduodenal contents refluxed from the stomach overcome the antireflux barrier of the upper oesophageal sphincter and diffuse into the aqueous environment typical of the oropharyngeal area, irritating and inflaming the mucous membrane of the laryngopharyngeal region and causing various symptoms, such as: dysphonia, need to clear the voice, need to scrape the throat, excess mucus in the throat, the sensation of retronasal discharge, chronic cough, pharyngeal globus with foreign body sensation.

The same symptoms can be associated with mucosal inflammation due to diseases of the upper respiratory tract. Here too, the protective barrier created by the hyaluronic acid in KAROS ORAL SPRAY relieves the painful symptoms of acute or chronic pharyngitis and laryngitis, and, thanks to hyaluronic acid's ability to attract and retain water, also helps to thin mucus.

INDICATIONS

KAROS ORAL SPRAY is indicated in the treatment of symptoms related to oropharyngeal mucosal inflammation (inflammation of the mucosa of the mouth up to the pharynx) such as inflammation of the vocal cords with and without dysphonia (voice disorders), hoarseness, need to clear the voice, need to scrape the throat, excess mucus in the throat, retronasal discharge sensation,

chronic cough, pharyngeal globus with foreign body sensation (feeling of constriction or foreign body in the throat), when these disorders are related to laryngopharyngeal reflux disease (LPR) or to diseases of the upper respiratory tract such as pharyngitis and laryngitis, both acute and chronic.

KAROS ORAL SPRAY is in addition to and does not replace other therapeutic treatments that may be prescribed to patients.

PACKAGE CONTENTS

KAROS ORAL SPRAY is a solution for oral administration.
The package contains one 20ml multi-dose bottle.

COMPOSITION

Each 20ml multi-dose bottle contains: 0.3% sodium hyaluronate (Hyaluronic Acid Sodium Salt), sodium chloride, potassium sorbate, sodium benzoate, citric acid, purified water.

FREQUENCY OF USE

2 puffs in the mouth 3 times a day, 1 hour after meals is recommended.
Continue treatment for a period of 2 weeks unless otherwise advised by your doctor.
Each spray delivers 140 microlitres of solution.

INSTRUCTIONS FOR USE

Press on the nozzle, directing the jet towards the bottom of the oral cavity.
Keep the bottle upright.
Shake before use.
Do not take food or drink for about 1 hour after treatment.

WARNINGS

Do not use KAROS ORAL SPRAY after the expiry date stated on the package.
Do not use KAROS ORAL SPRAY if the packaging is open or damaged.
Do not take food or drink for about 1 hour after treatment with KAROS ORAL SPRAY.
Store between 0° and 25°C. Do not freeze.
Once used, dispose of the bottle according to the normal rules for differentiated disposal of household waste.
Consult your doctor before using KAROS ORAL SPRAY.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

INTERACTIONS

There are currently no known interactions between KAROS ORAL SPRAY and any concomitant therapies.
However, as KAROS ORAL SPRAY consists of saline solution and hyaluronic acid, a natural constituent of human tissue, such interactions are, in principle, to be excluded.

CONTRAINDICATIONS AND SIDE EFFECTS

There are currently no known contraindications to the use of KAROS ORAL SPRAY, nor have any side effects been reported, nonetheless the product must not be used in case of known hypersensitivity to sodium hyaluronate or the other components. If you experience any undesirable effects, you should stop treatment and consult your doctor.

DATE OF LAST REVISION OF PACKAGE LEAFLET June 2021

Shelf-life: 36 months

The expiry date indicates the maximum shelf-life of the medical device

MANUFACTURER









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DISTRIBUTOR

(Name and address of distributor)

			
	Storage temperature	Carefully read the warnings	See the instructions for use
			
Use by...	Batch	Manufacturer	Do not use if the package is damaged