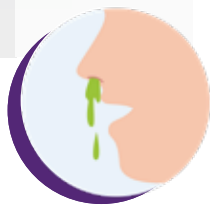


CLINICAL TRIAL

Rinofast: *Clinical Study* on Nasal Congestion



CLINICAL TRIAL ENDPOINTS



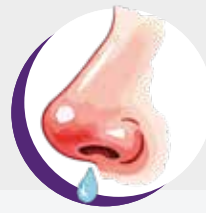
NASAL CONGESTION



RHINOSINUSITIS



RHINITIS



**ASSOCIATED SINONASAL
SYMPTOMS**

PROSPECTIVE OBSERVATIONAL CLINICAL STUDY



20 Patients



**1–2 sprays per
nostril, 2–3
times a day for
14 days**

EVALUATION OF NASAL CONGESTION

Through

Sino-Nasal Outcome Test (SNOT-22)

RESULTS OF THE TRIAL

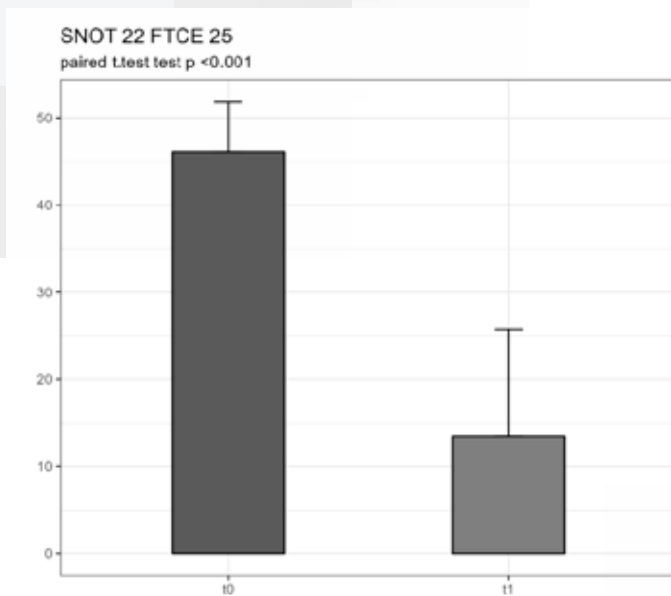


Figure 1. SNOT-22 Questionnaire overall score, before (T0) and after(T1) the treatment

Overall Evaluation of symptoms before and after treatment

After 14 days of treatments:

- Mucus Secretion (-85%)**
- Runny Nose (-75%)**
- Nasal Congestion (-67%)**
- Cough (-80%)**

Read More

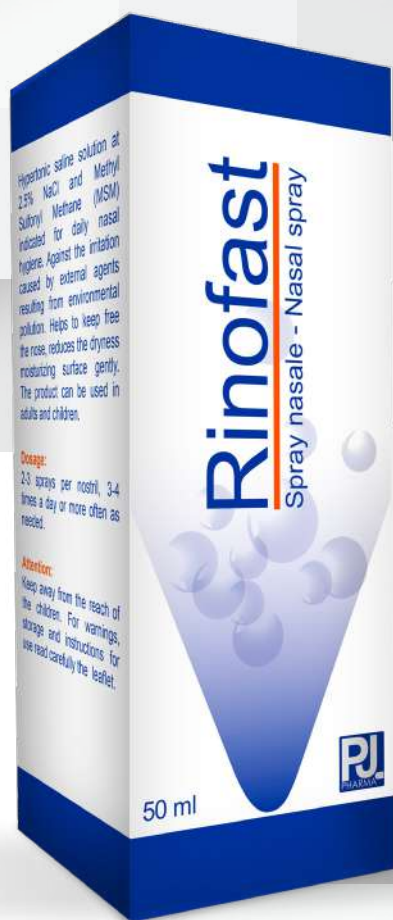


Rinofast

nasal spray



Ideal for
children



- Cold
- Nasal dryness
- Allergic rhinitis
- Nasal hygiene

Medical Device **CE**



MADE IN ITALY

CHILDREN'S COLD

PLUS

DESCRIPTION

Rinofast is a hypertonic saline solution at controlled pH for daily nasal hygiene useful against the irritation caused by external agents. Thanks to its osmotic, fluidifying and protective action, Rinofast helps even in case of colds, rhinorrhea and allergic rhinitis.

Rinofast is based on:

- Methyl-sulfonyl methane (MSM - 1%)
- Sodium chloride (2,5%)

It is suitable for adults and for children.



2 - 3 sprays per nostril, 3 - 4 times a day, or more if needed.

THERAPEUTIC INDICATIONS

- Colds
- Rhinorrhea
- Allergic rhinitis
- Nasal dryness

PRESENTATION

50mL solution in a glass bottle equipped with nasal spray dispenser

INGREDIENTS

Aqua, Sodium Chloride, Methyl - Sulfonyl - Methane (MSM), Citric Acid, Potassium Citrate e Sodium Dehydroacetate.

REGULATORY STATUS

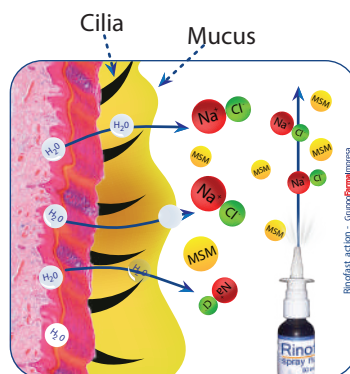
- Class I
- Free sale certificate
- Declaration of conformity CE
- Certificate of origin
- ISO 13485 certificate

DOUBLE ACTION:

● NaCl 2,5%

OSMOTIC ACTION

Immediate

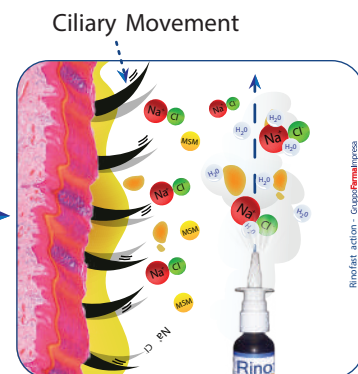


The first image shows the decongestant and fluidizing action of Rinofast, thanks to the osmotic action of the hypertonic saline solution and to the antioxidant action of MSM.

● MSM

ANTIRADICAL ACTION

Protective



The second image shows the improvement of the functionality of the nasal mucosa, thanks to the increase of mucociliary clearance activated by the action of hypertonic solution.

NaCl al 2.5% HIGHER TOLERABILITY

- Constant volume for each spray.
- Moreover, the conical jet is more delicate and permits the utilization even when the nasal mucosa is more sensitive (in children or in case of irritation).



CLINICAL TEST

RISK ANALYSIS - according to UNI CEI EN ISO 14971:2012

BIOCOMPATIBILITY according to UNI EN ISO 10993:

- NASAL MUCOSA IRRITATION TEST according to UNI EN ISO 10993-10

CLINICAL EVALUATION - according to MEDDEV 2.7-1

STABILITY - according to ICH Guidelines:

- ACCELERATED STABILITY STUDY
- LONG TERM CHALLENGE TEST according to F.U.