



# French innovation in topical medical devices.

A patented polymeric platform for market-ready nasal, throat and oral care products.

MDR Class IIa medical devices

ISO 13485 manufacturing

Patented polymeric technology

Private label for distributors

# One platform. Multiple market-ready medical devices.

Vitrobio is a **family-owned company** that designs, develops and manufactures **Class IIa topical medical devices** based on a **patented technology** — a filmogenic glycerol-based polymeric platform. The same scientific foundation supports a complete portfolio of nasal, throat, cough, pediatric and oral care products, ready to be launched under your brand.

01

## Innovation

**Patented filmogenic glycerol technology.** 4–6 h surface residence. Multi-target local action.

02

## Regulatory

**MDR-compliant Class IIa** medical devices. CE 0459 — GMED notified body. Complete technical files.

03

## Clinical

**Clinical studies supporting key products.** Local, non-systemic, mechanical and physico-chemical mode of action.

04

## Commercial

Private-label model proven with leading pharma partners. **Turnkey products under your brand name.**

*One technology, one manufacturer, one private-label partner.*

# A portfolio built around high-potential pharmacy categories.

*Multiple ready-to-market solutions across recurring, high-demand needs.*

Category	Needs covered / indications	Portfolio depth	Market signal
<b>Cough &amp; Cold</b>	Blocked nose, rhinosinusitis, sinusitis, throat infection, dry/wet cough	Multiple nasal, throat and syrup solutions	<b>\$91B market</b>
<b>Allergy</b>	Allergic rhinitis, pediatric allergy, pollution-induced allergy	Adult, pediatric and environmental allergy solutions	<b>\$18B by 2035</b>
<b>Neurology</b>	Migraine prevention support	Specialty nasal medical device concept	<b>9.7% CAGR</b>
<b>Oncology supportive care</b>	Oral mucositis, dry mouth, lesion protection	Specialty oral care solution	<b>7.6% CAGR</b>
<b>Kids</b>	Pediatric allergy, cough, throat, nasal congestion	Dedicated pediatric range	<b>\$14B by 2036</b>
<b>Oral &amp; labial care</b>	Cold sores, oral ulcers, local oral lesions	Targeted local lesion-care solutions	<b>6.7% CAGR</b>

**Each category can be activated through ready-to-market private-label products.**

CAGR : Compound Annual Growth Rate. Source: [The Business Research Company — Cough & Cold Preparations](#), [Market Research Future — Allergic Rhinitis](#), [Coherent Market Insights — Migraine Drugs](#), [Coherent Market Insights — Oral Mucositis](#), [Fact.MR — Pediatric Allergy Care](#), [Coherent Market Insights — Cold Sore Treatment](#)

AMONG OUR PARTNERS



# PRODUCTS RANGE



Allergy



Throat infections



Rhinosinusitis



Cough



Migraine Prevention



Oral Mucositis



Oral ulcers



Labial herpes



Child Range

# Vitrobio: Innovation and R&D rewarded.

Vitrobio's research began **25 years ago** and is still ongoing. Several **awards** have recognised the key milestones in our work.

## Our Awards



Prince Louis de Polignac  
awarded by  
**the French Academy of Science**



2021 **French National Assembly  
Award** for *Research contribution*



**European PAEXA Award**  
*In vitro technology*

## Our research partners



**INSERM**: French National Institute of  
Health and Medical Research



**Neuro-Dol**: European Centre for  
Research on Migraine and Pain



**CHU**: University Hospital Centre for  
Clinical Research

**CLERMONT-FERRAND**

CENTRE HOSPITALIER UNIVERSITAIRE

# Disease is multi-factorial.

*Treating only one factor leaves the rest active. A multi-target topical approach is needed.*

1

## Disease triggers

Allergens, pollutants, viruses, irritants



2

## Initial cellular damage

Cell death, cellular debris

3

## Secondary bacterial contaminants



6

## Chronic disease & repeated infection

## Disease physiopathology

4

## Immune trigger & Inflammatory cascade

Liberation of disease specific proteins.

Ex : Cytokines, Interleukines, Histamines, TSLP, MMP, TNF $\alpha$  ...


5

## Broken cellular barrier

# Currently available treatment

Treating only one factor leaves the rest active. A multi-target topical approach is needed.

1 Disease triggers  
→ Masks



2 Initial cellular damage  
→ Saline solution,  
sea water

3 Secondary bacterial  
contaminants  
→ Antiseptics,  
antibiotics

6 Chronic disease & repeated  
infection  
→ None

Available  
treatments


4 Immune trigger &  
Inflammatory cascade  
→ Anti-inflammatory,  
anti-histamine.  
*Mono Target only*

5 Broken cellular barrier  
→ None

# The multi-target approach

When a live biological surface is clean & Free of contaminants: It heals immediately

1 Disease triggers  
→ Block



2 Initial cellular damage  
→ Stop

3 Secondary bacterial contaminants  
→ Remove

6 Chronic disease & repeated infection  
→ Supress

**Multi-target**  
*Should act on all the paramaters*

4 Immune trigger & Inflammatory cascade  
→ Stop

5 Broken cellular barrier  
→ Repair

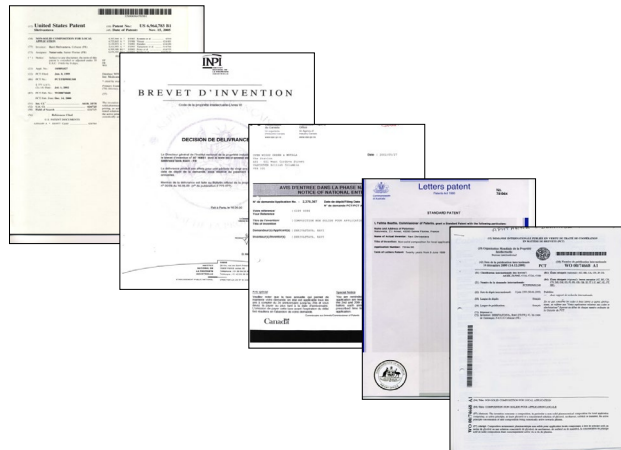
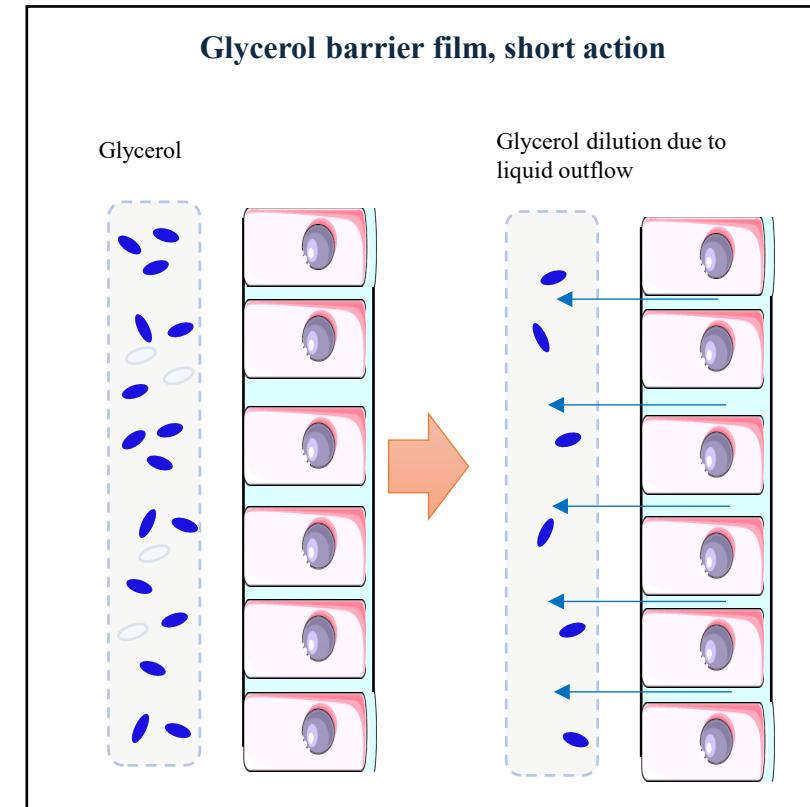
# STEP 1 : Finding a non-irritant osmotic surface cleaning solution

*Identical to sea water but non-irritant & much more osmotic*

**VB-Gy glycerol:** 18 times more osmotic than sea water, yet not cytotoxic.

→ creates a strong outward flow of hypotonic liquid to detach, drain & clean all surface contaminants.

→ Inconvenient: **Short action** (*dilution due to liquid outflow*)



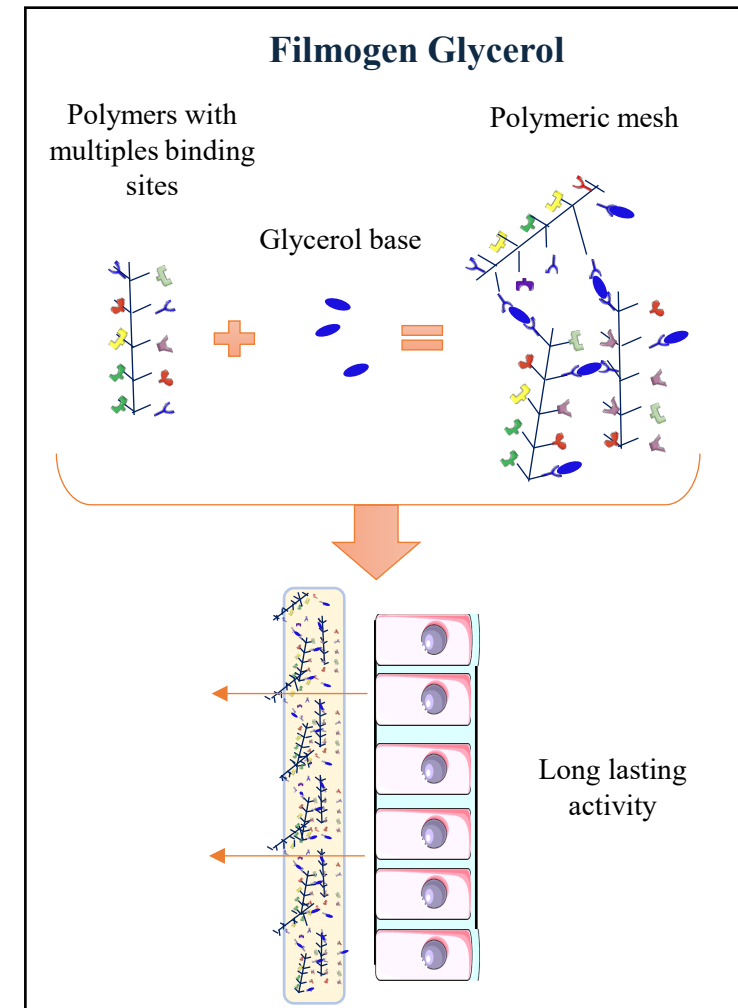
Patent (2000-2005)

# STEP 2 : Rendering the solution filmogen

VB-Gy glycerol + **Glycerol binding specific polymers**

= Mesh-like osmotic film → Filmogen Glycerol

→ Inconvenient: **Irritant to fragile tissues (nasal mucosa)**



# STEP 3 : Rendering the film non-irritant and absorbent

Adding a few selected jellifying or thickening agents.

The filmogen Glycerol technology was patented in 2011

→ **Inconvenient:** Not able to trap the disease specific & inflammatory proteins

**WORLDWIDE PATENT**

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau

(43) International Publication Date  
14 July 2011 (14.07.2011)

(10) International Publication Number  
**WO 2011/082835 A1**

PCT

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*A61K 36/537* (2006.01) *A61P 31/12* (2006.01)  
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(71) Applicant (for all designated States except US): VITRO-BIO SARL [FR/FR]; ZAC de Lavauz, F-63500 Issire (FR).

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Published:  
— with international search report (Art. 21(3))

WO 2011/082835 A1

(54) Title: NEW SYNERGISTIC COMPOSITIONS FOR THE TREATMENT OF TOPICAL VIRAL INFECTIONS

(57) Abstract: The invention concerns a synergistic composition comprising plant extracts rich in terpenes for the treatment of topical viral infections, the plant extracts containing at least one protease inhibitor and/or at least one viral glycoprotein inhibitor.

## STEP 4 : Block & neutralize selected proteins

This research project was based on a simple observation:

1. Skin contains many proteins!
2. All these proteins are blocked simultaneously to convert skin into leather!
3. Specific tannins (polymers) are used to block each skin protein.

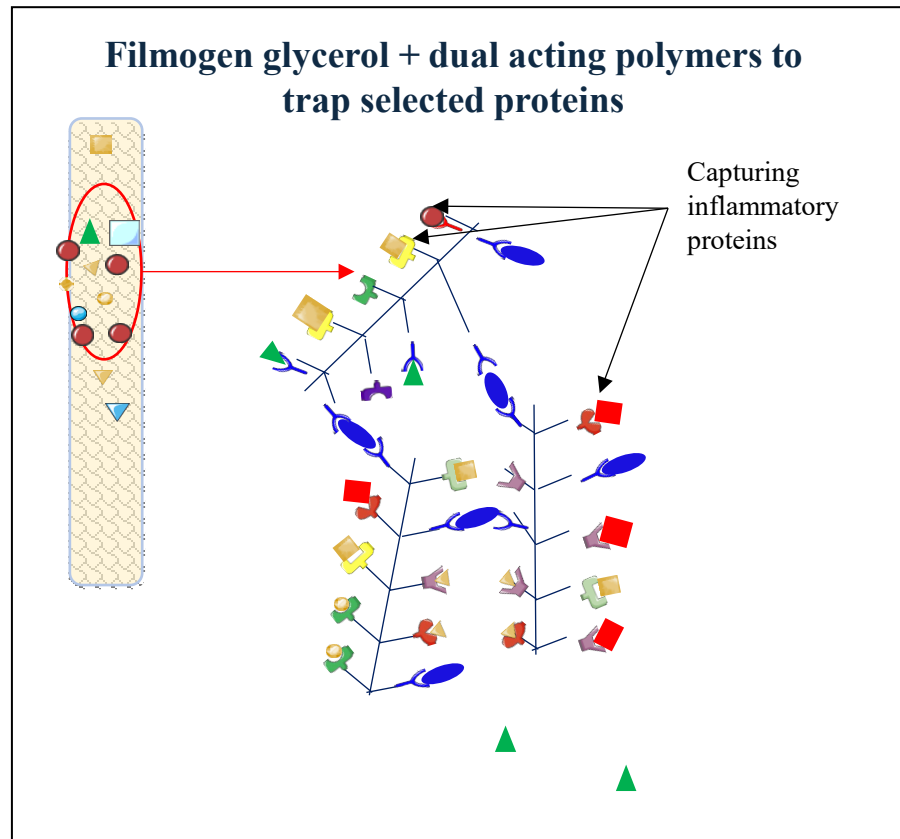
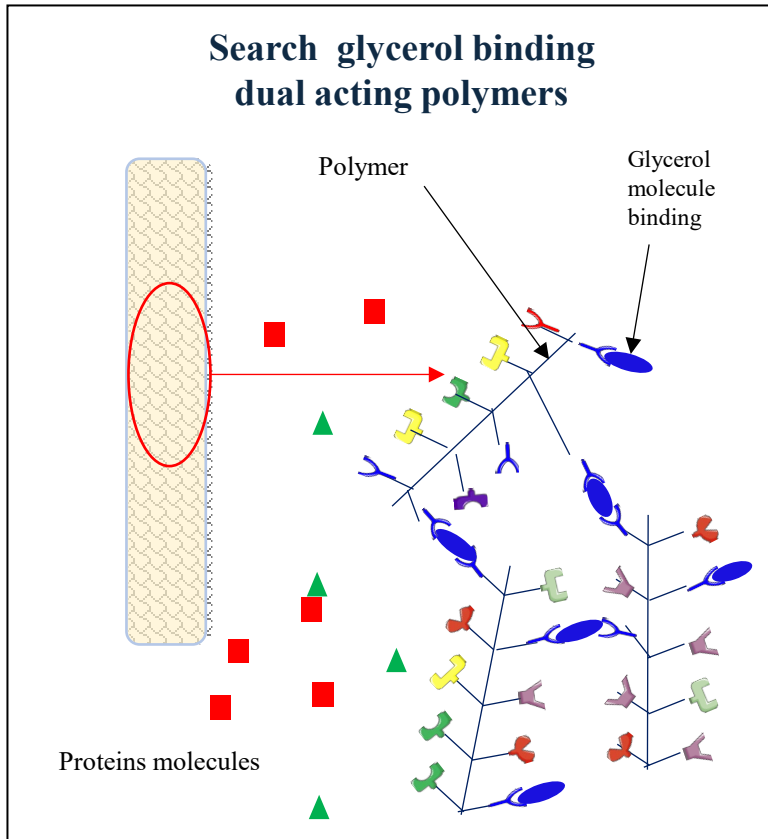
**→ Use the same technology to block disease specific & inflammatory proteins !**



After natural, chemical & biological drugs, polymers may constitute a new generation of selective protein inhibiting drugs in the future

# STEP 4 : Block & neutralize selected proteins

Searching big polymers which can bind with glycerol + disease specific proteins



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WIPO PCT

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 (71) Applicant: VITROBIO SAS [FR/FR]; ZAC de Lavaur, 63500 ISSOIRE (FR)  
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 (71) Applicants: SHRIVASTAVA, Léa [FR/FR]; 43Bis, Route de Châteauguay, 63118 CÉBAZAT (FR); SHRIVASTAVA, Ravi [FR/FR]; 137, rue Claude Debussy, 63110 BEAUMONT (FR)  
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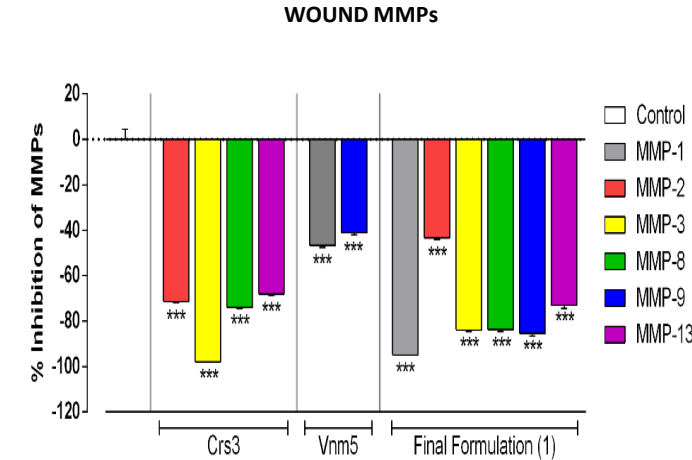
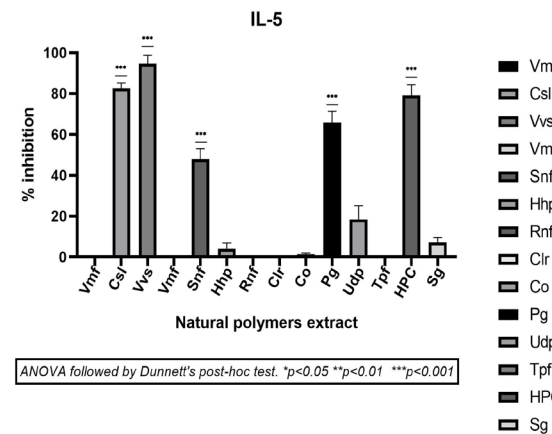
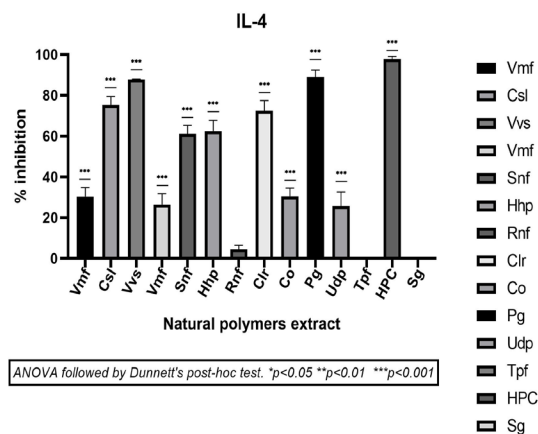
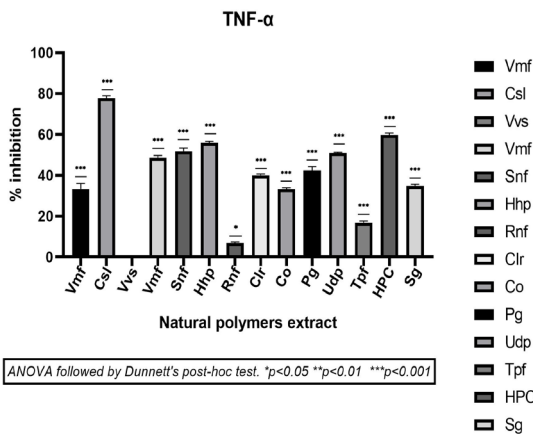
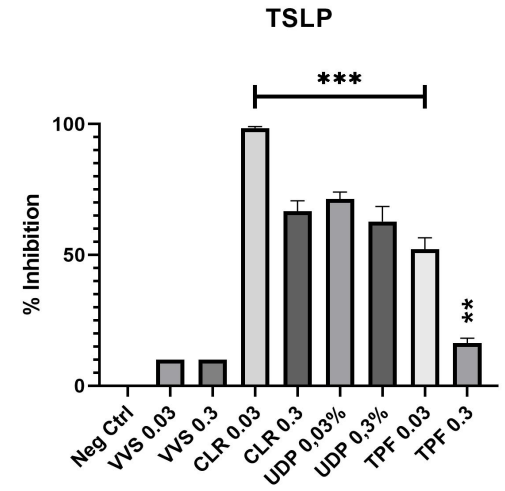
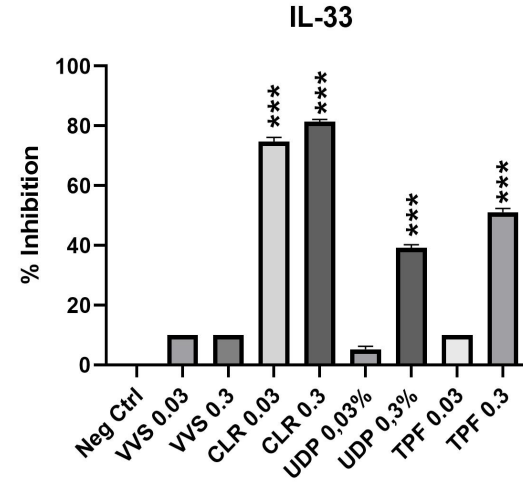
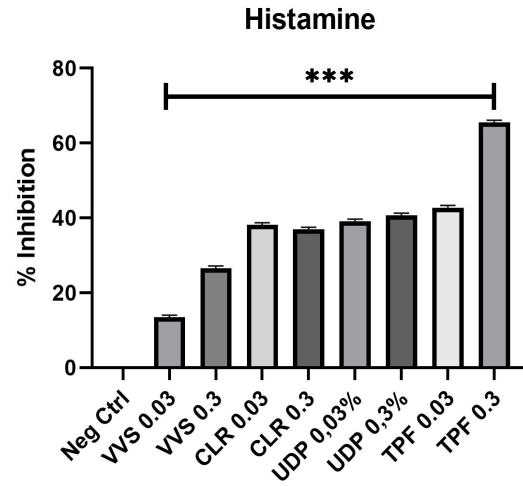
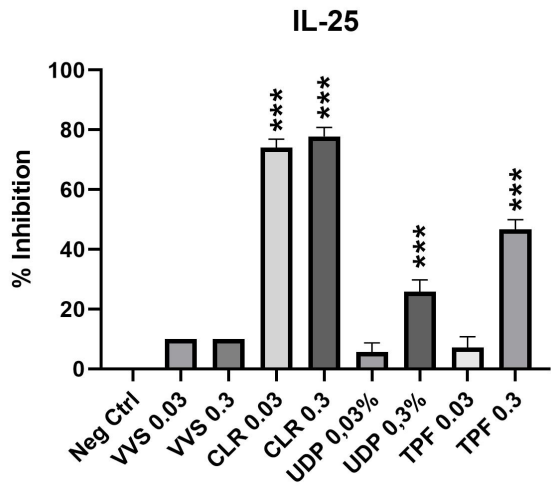
Published with international search report (Art. 21(3))

(54) Title: DUAL ACTING POLYMERS IN AN OSMOTIC FILM FOR TOPICAL APPLICATION TO TREAT INFLAMMATORY DISEASES AND CYTOKINE RELEASE SYNDROME  
 (57) Abstract: The invention relates to methods and compositions for the prevention and the treatment of topical inflammatory diseases and their consequences, in particular CRS. The compositions for topical use of the invention comprise dual acting polymers that are bound to glycerol and able to further bind to at least one pro-inflammatory compound.

WO 2022/053128 A1

Dual acting polymers Patent (2022)

# STEP 4 : Identifying & blocking key proteins (Examples)

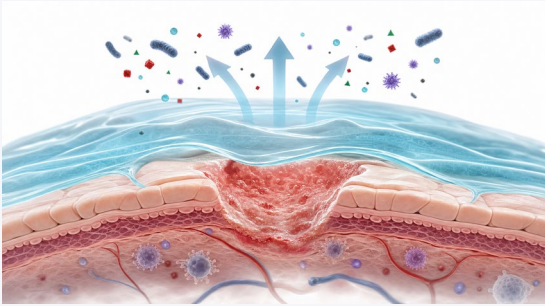


# A four-step local mechanism of action

A filmogenic polymer layer designed to protect, clean, capture and support tissue recovery.

01

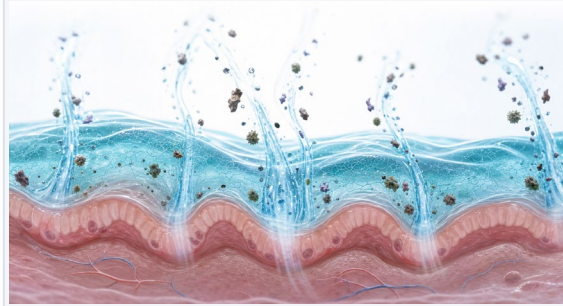
**Protect**



Forms a **protective film** over the lesion and limits exposure to new contaminants.

02

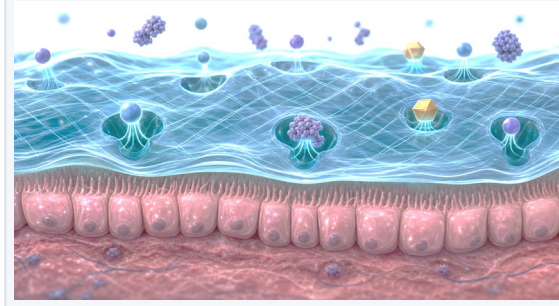
**Clean**



Clean continuously all the **surface contaminants**, debris and irritants.

03

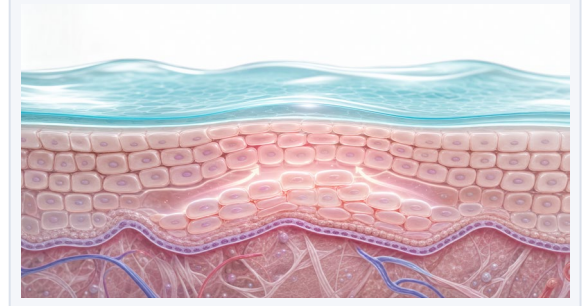
**Capture**



Selected polymers **capture** **disease-related proteins** and inflammatory mediators within the film.

04

**Support recovery**



Establish **conditions for cell-growth** to reconstitute tissue barrier & defense

# Why it matters for patients and pharmacists.

Vitro bio's local, mechanical mode of action translates directly into an easy pharmacy story: a credible product that pharmacists can recommend with confidence, including for repeat and pediatric use.

## Local action

Acts where symptoms occur. No need to reach a systemic target.

## Non-systemic positioning

Limited systemic exposure: a strong argument for sensitive populations.

## Multi-target local approach

Addresses triggers, surface contaminants and mediators in one product.

## Suitable for recurring needs

Designed for chronic and seasonal indications, repeated daily use.

## Easy pharmacy recommendation

Clear positioning: medical device, French manufacturing, clinical data.

# A complete portfolio of ready-to-market topical medical devices

## Cough & Cold

- Nesospray** — rhinosinusitis / blocked nose
- Nesospray Kids** — pediatric rhinosinusitis
- Pharyndol** — throat infection / irritation
- Pharyndol Kids** — pediatric throat care
- Cough Spray** — dry & wet cough support
- Cough Kids** — pediatric cough support

*Coming soon · cough & throat syrup*

## Allergy

- Allerspray** — allergic rhinitis
- Allerspray Kids** — pediatric allergic rhinitis
- Allerpur / PCNS** — pollution & environmental allergy

## Pediatric Range

- Allerspray Kids** — allergic rhinitis
- Nesospray Kids** — rhinosinusitis
- Pharyndol Kids** — throat care
- Cough Kids** — cough support

*Dedicated children's range across allergy, nasal, throat & cough*

## Oral & Labial Care

- Oralherp** — labial herpes / cold sores
- Oroheal** — oral ulcers / canker sores

## Oncology Supportive Care

- Orosol** — oral mucositis / dry mouth

## Neurology

- Migspray** — migraine prevention

READY FOR MARKET

### Your brand on our medical devices

- Private label / distributor-owned brands
- Ready-to-market products
- Turnkey technical files

**MD**  
MEDICAL  
DEVICE

**CE**  
0459 · GMED

**ISO**  
13485

**MDR**  
2017/745

# Coming soon: new launch opportunities within 8-15 months.

01

COMING SOON

## Cough & throat syrup

Class IIa medical device  
~8-12 months

- 3 formulations
- Sugar free
- With or without honey
- Age : 3+
- 125ml glass or PET bottle
- Child safety cap
- Patented technology
- MDR 2017-745



02

COMING SOON

## Premium oral spray supplements

Food supplement platform ·  
~9-15 months

- Premium oral sprays : 100% natural, free of controversial ingredients. Yuka-friendly
- Sleep, immunity, energy, sport, stress, vitamins, women's health, kids...
- Microencapsulation : The active ingredients are easily absorbed through the sublingual route
- Patented technology

03

COMING SOON

## Saline-adjuvant nasal range

Class IIa medical device ·  
~12-24 months

- It's official: seawater-based sprays have been reclassified as Class IIa.
- Vitrobio has decided to expand its product line by combining its technology with saline water.
- MDR 2017-745



# Ready-to-market medical devices under your brand.

## Regulatory readiness

### MDR 2017/745

Compliant with the EU Medical Devices Regulation.

### CE 0459 – GMED

Notified body certification for Class IIa devices.

### ISO 13485

Quality management system for medical devices.

### Technical files

Complete technical documentation available for partners.

### Clinical data

Studies supporting key product claims.

## Integrated manufacturing

*Vitrobio site · Issoire, Auvergne, France*

- 1 Research & Development
- 2 Manufacturing
- 3 Filling
- 4 Packaging

*Designed, developed and manufactured in France — full value chain under one roof.*

# Already trusted by leading pharmaceutical partners.

# 20+

countries with Vitro bio products available

# Major

pharma partners including Sanofi, UPSA, Urgo and Uriach

# 30+ yrs

of polymeric R&D and medical device experience

## Selected partnerships

STADA - Walmark

UPSA

Urgo

Uriach

Menarini

Bouchara Recordati

*Proven private-label model for pharmaceutical and healthcare brands.*

# Why partner with VitroBio now.

**01**

## Patented technology

A unique filmogenic glycerol platform — defensible, proven, scientifically credible.

**02**

## Market-ready portfolio

Class IIa products covering high-demand OTC categories.

**03**

## Private-label model

Turnkey approach: your brand, your packaging, our manufacturing.

**04**

## Regulatory readiness

MDR 2017/745 compliant, CE 0459, ISO 13485 — files ready to share.

**05**

## French manufacturing

Full value chain in Issoire, France — R&D, production, filling, packaging.

**06**

## Always innovating

Syrup, oral spray supplement platform, saline-adjuvant nasal range.

*MDR evolutions and growing demand for non-systemic topical solutions create a timely market window.*

**Want to learn more  
about a specific product**





Example of a product visual

**COMPOSITION**  
 Filmogenic glycerol, Allercyanidin (from plant-based ingredients), essential oils.

**PRESENTATION**  
 15 ml nasal spray (approx. 125 sprays).

## DESCRIPTION

ALLERSPRAY is a Class IIa medical device indicated for the **prevention & treatment of allergic rhinitis (dust, mites, pollens, pets...)**. Utilizing innovative technology based on natural polymers, ALLERSPRAY forms an osmotic, stable, and non-irritating film against seasonal allergens and provides quick relief. ALLERSPRAY is MDR approved and supported by clinical studies.

- 1. Protect from allergens
- 2. Cleans the nasal mucosa
- 3. Reduces inflammatory markers
- 4. Captures allergens

## CLINICAL STUDIES

Two clinical studies were conducted: one randomized vs placebo and a single-arm observational study. Results showed exceptional efficacy on nasal and ocular symptoms.

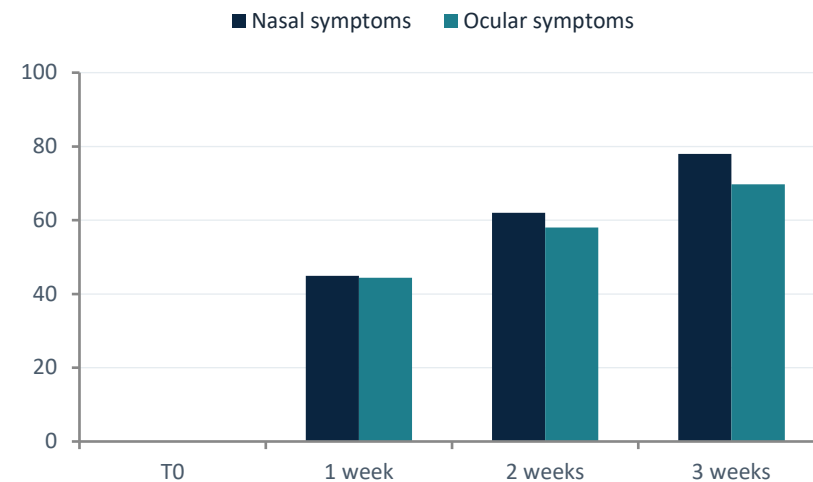
- Nasal symptoms ↓ 44.9% vs 11.7% (comparator) at Week 1; up to 78% at Week 3.
- Ocular symptoms (rTOSS) ↓ 44.4% at Week 1; up to 69.7% at Week 3 vs 15.8% (comparator).

Shrivastava & al. 2017 — Journal of Allergy & Therapy

## EXAMPLES OF SOME CLAIMS

- Fast relief from allergy symptoms
- Relieves nasal congestion, runny nose, sneezing and nasal itching
- Immediate eye comfort from the first days
- Relieves itchy, watery, and red eyes
- Helps prevent allergy symptoms
- Up to 78% reduction in nasal allergy symptoms

Symptom reduction over time (%)



Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand

# ALLERSPRAY KIDS

Treatment of allergic rhinitis in children

3+



Example of a product visual

## DESCRIPTION

ALLERSPRAY KIDS is a Class IIa medical device indicated for the treatment of allergic rhinitis in children. Based on natural polymers, it forms an osmotic, stable, and non-irritating film on the nasal surface against allergens and environmental contaminants. MDR approved and supported by clinical studies.

1. Protect from allergens

2. Cleans the nasal mucosa

3. Reduces inflammatory markers

4. Captures allergens

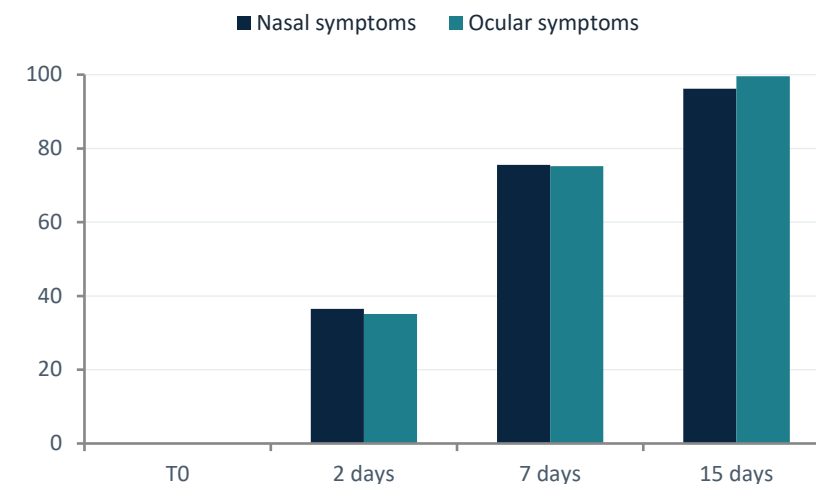
## CLINICAL STUDIES

A placebo-controlled clinical trial in children confirmed the results obtained in adults. No adverse event was reported.

- Nasal symptoms ↓ 36.5% vs 22% (comparator) at Day 2; up to 96.2% at Day 15.
- Ocular symptoms ↓ 35.1% vs 21.1% at Day 2; up to 99.6% at Day 15.
- Congestion & itching relief noticeable in 30 minutes; 59.4% improvement at Day 2.
- Antihistamine use: only 5% of children needed rescue meds vs 70% (comparator).

Shrivastava & al. 2021 — J. Clinical Research and Reports

Symptom reduction over time (%)



## COMPOSITION

Filmogenic glycerol, solagum, Allercyanidin-E (from plant-based ingredients).

## PRESENTATION

15 ml nasal spray (approx. 125 sprays).

## CLAIMS

- Fast relief of nasal allergy symptoms
- Soothes itchy and congested nose within minutes
- Relieves eye symptoms caused by allergies
- Improves sleep and well-being
- Reduces need for antihistamines
- Safe and well tolerated by children

Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand



## DESCRIPTION

ALLERPUR is a Class IIa medical device indicated for the treatment of respiratory symptoms induced by allergens from pollution. Based on natural polymers, it forms an osmotic, stable, and non-irritating film on the nasal surface. MDR approved and supported by clinical studies, providing effective protection against environmental allergens and contaminants.

1. Protect from allergens & pollution

2. Cleans

3. Reduces inflammatory markers

4. Captures allergens

## CLINICAL STUDIES

The clinical study showed significant results for all nasal and ocular symptoms. No significant adverse side effects were reported.

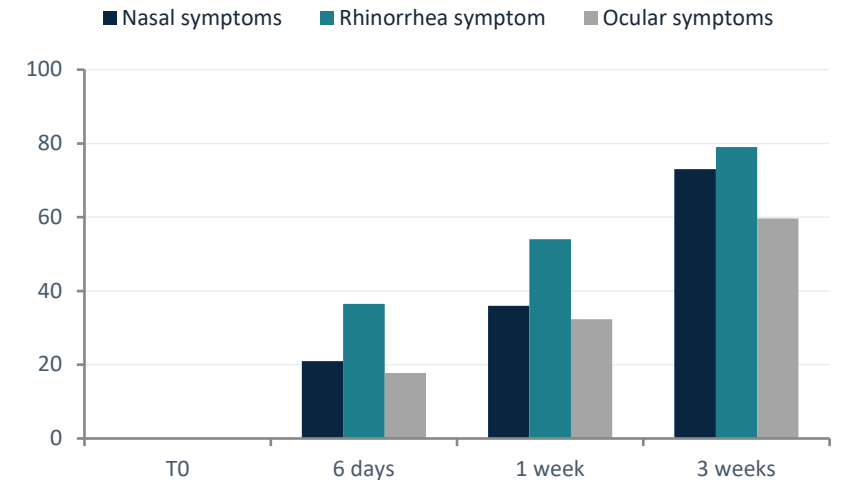
- Nasal symptoms ↓21% vs 5% at Day 6; ↓ 36% vs 15% at Day 12.
- Rhinorrhea symptom ↓ 36.5% vs 22% at Day 6; ↓ 54% vs 32% at Day 12.
- Ocular symptoms ↓ 17.8% vs 8.6% at Day 6; ↓ 32.3% vs 9.5% at Day 12.
- Respiratory symptoms ↓ 40.49% vs 15.39%.
- Eosinophil count: ↓ from 14.95 to 4.33.
- Quality of Life improved by 46.65%.

Shrivastava & al. 2021 — J. Clinical Research and Reports

## CLAIMS

- Fast relief from nasal allergy symptoms
- Up to 79% reduction in rhinorrhea symptom
- Significantly reduces nasal congestion

Symptom reduction over time (%)



- Relieves runny nose and sneezing
- Improves breathing and reduces cough
- Soothes itchy, watery eyes

## COMPOSITION

Filmogenic glycerol, HPC, Pollucyanidin-P (from plant-based ingredients), essential oils.

## PRESENTATION

15 ml nasal spray.

Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand

# COUGH SPRAY

Treatment of acute dry or productive cough

8+



Example of a product visual

## COMPOSITION

Filmogenic glycerol, honey, CDN-Cyanidin (from plant-based ingredients), essential oils.

## PRESENTATION

30 ml throat spray.

## DESCRIPTION

COUGH SPRAY is a Class IIa medical device indicated for the **treatment of cough**. Based on natural polymers, it forms a protective film on the throat surface. The osmotic action provides continuous cleaning by mechanically removing contaminants, helping to keep the throat surface clean and hydrated and to reduce inflammation and coughing. MDR approved and supported by clinical studies.

1. Protects and soothes

2. Muco-regulation

3. Reduces the cough reflex

## CLINICAL STUDIES

Clinical studies on similar formulations have demonstrated the effectiveness of our cough products in relieving dry and productive coughs, reducing the need for antibiotics, and improving quality of life.

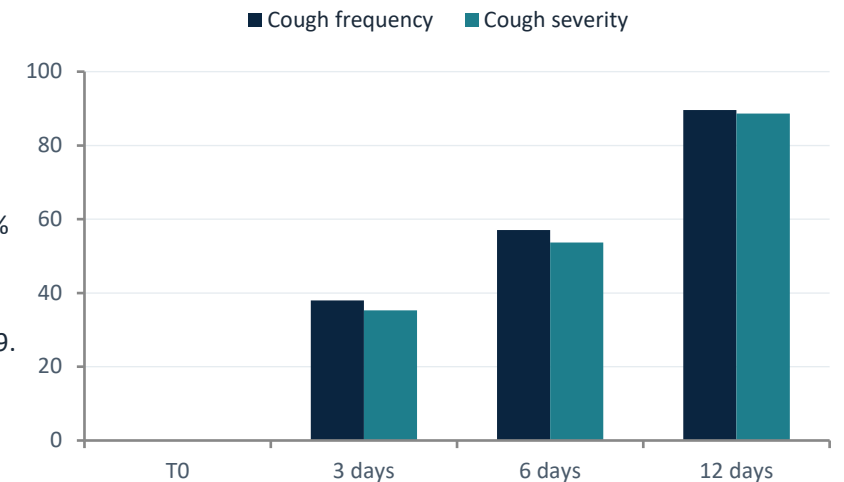
- Cough severity ↓ 20% vs 0% (comparator) at Day 2; ↓ 73,3% vs 5,6% at Day 9.
- Cough frequency ↓ 38% vs 4,4% at Day 3; ↓ 77% vs 10,2% at Day 9.
- Chest discomfort ↓ 14% at 2h post-treatment; ↓ 90% vs 7% at Day 9.

Shrivastava & al. 2017 — J. Pulmonary & Respiratory Medicine

## CLAIMS

- Significantly reduces cough severity
- Reduces cough frequency from Day 2
- Fast relief from chest congestion
- Improves sputum quality
- Minimizes need for antibiotics
- Enhances quality of life

Cough metrics reduction over time (%)



Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand

Treatment of throat infections (pharyngitis, tonsillitis, rhinopharyngitis, sore throat — viral or bacterial)



Example of a product visual

## DESCRIPTION

PHARYNDOL is a Class IIa medical device indicated for the treatment of throat infections including pharyngitis, tonsillitis, rhinopharyngitis and sore throat of viral or bacterial origin. Based on natural polymers, it forms a protective film on the throat surface. The osmotic action provides continuous cleaning by mechanically detaching and draining surface contaminants and inflammatory proteins. MDR approved and supported by clinical studies.

1. Protects from irritants

2. Soothes and calms

3. Breaks the irritation–inflammation cycle

## CLINICAL STUDIES

The randomized, double-blind clinical study showed results on throat pain within two hours of application, with improvement across all parameters related to throat infections and no side effects reported.

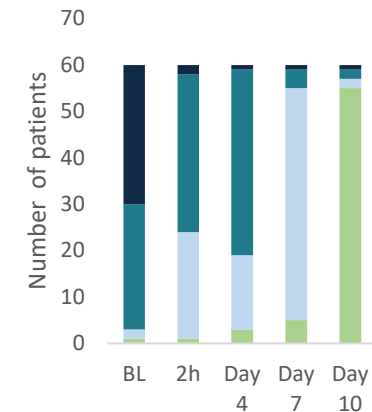
- Throat pain : only 2 patients recorded severe pain 2 hours after the first application and ↓ significantly by day 4
- Throat redness ↓ significantly by Day 4.
- Bacterial load ↓ from >1950 CFU to 1887.2 CFU 2 hours after the first application, then to 745.6 CFU on Day 4, 374.9 CFU on Day 7, and complete absence of detectable bacteria by Day 10.
- Complete recovery: 31.7% at Day 2 vs 11.6% (placebo).
- Need for antibiotics: only 6.7% vs 32.6% (placebo)

Shrivastava & al. 2011 — Journal of Clinical Trials

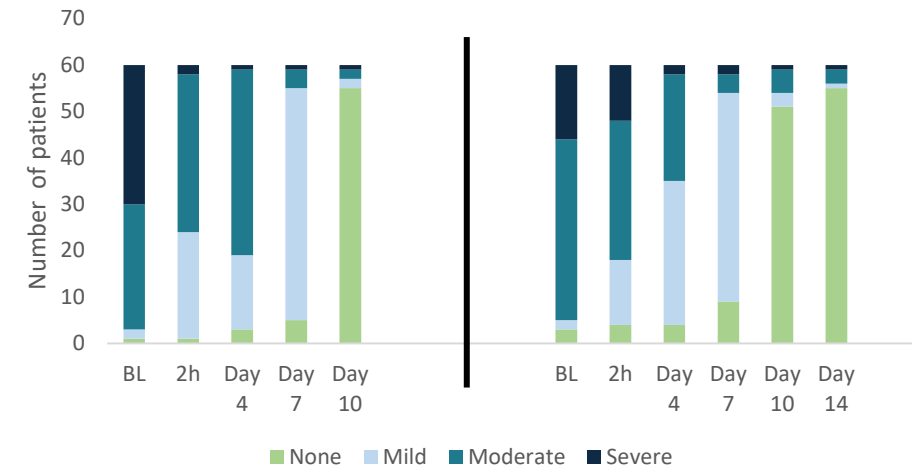
## CLAIMS

- Fast relief from sore throat pain and irritation
- Soothes throat irritation within 2 hours
- Reduces throat redness and inflammation quickly

### Throat pain



### Throat redness



## COMPOSITION

Filmogenic glycerol, honey, Glycoyanidin-A (from plant-based ingredients).

## PRESENTATION

30 ml throat spray.

Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand



Example of a product visual

## COMPOSITION

Filmogen glycerol, honey, Glycoyanidin-E-N (from plant-based ingredients).

## PRESENTATION

20 ml throat spray.

## DESCRIPTION

PHARYNDOL KIDS is a Class IIa medical device indicated for the treatment of throat infections (pharyngitis) in children. Based on natural polymers, it forms a filmogen, stable, and non-irritating protective layer on the throat surface, providing relief from irritation and dryness. MDR approved and supported by clinical studies.

1. Protects from irritants

2. Soothes and calms

3. Breaks the irritation–inflammation cycle

## CLINICAL STUDIES

The results of the randomised, double-blind clinical trial conducted in children confirmed the results obtained in adults; no adverse effects were reported.

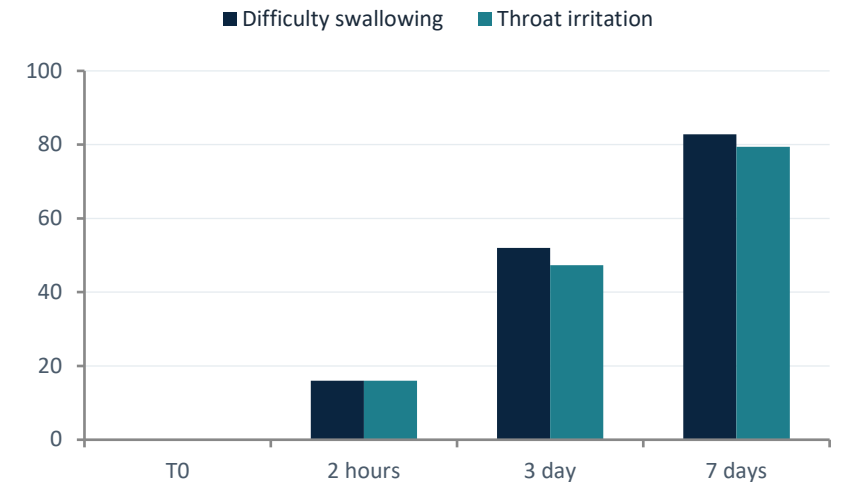
- Swallowing difficulty reduced by 52% vs 15% (placebo) by Day 3.
- Throat irritation reduced by 47,3% vs 32% (placebo) by Day 3.
- Antibiotic use required in only 15% of children vs 40% (placebo).
- Whitish bacterial deposits decreased by 56% vs 22% by Day 3 (placebo).

Shrivastava & al. 2021 — J. Clinical Research and Reports

## CLAIMS

- Fast relief from sore throat pain
- Reduces throat inflammation
- Soothes throat irritation quickly

Throat metrics reduction over time (%)



- Helps reduce the need for antibiotics
- No side effects observed
- Highly rated by doctors and parents

Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand



Example of a product visual

## COMPOSITION

Filmogenic glycerol, Rhinocyanidin (from plant-based ingredients).

## PRESENTATION

15 ml nasal spray.

## DESCRIPTION

NESOSPRAY is a Class IIa medical device indicated for the treatment of rhinosinusitis, rhinitis, and nasal congestion. Based on natural polymers, it forms a filmogen, stable, osmotic film on the nasal mucosa. The mechanical cleaning action generated by osmosis helps to detach and drain surface contaminants and to decongest the nasal passages. MDR approved and supported by clinical studies.

1. Protects from contaminants & particles

2. Flushes out contaminants & mucus

3. Breaks the inflammation cycle

## CLINICAL STUDIES

The double-blind, placebo-controlled clinical study showed significant results within 30 minutes of use and did not reveal any adverse effects.

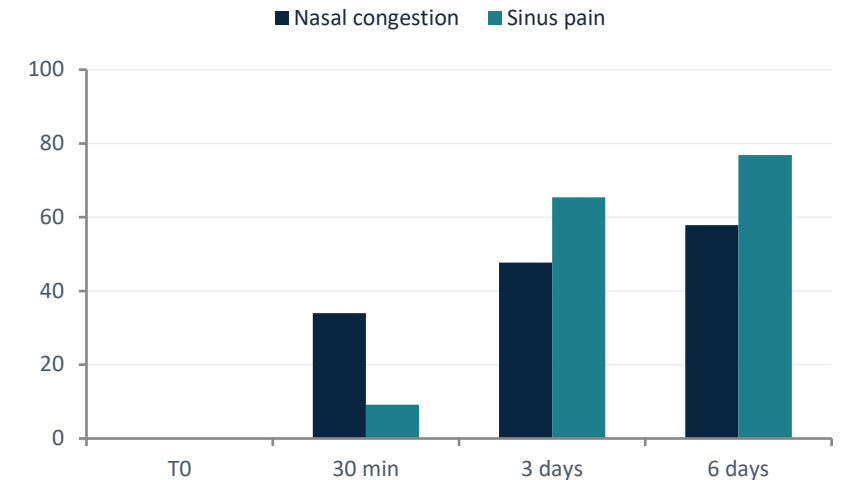
- Nasal congestion ↓ 34% within 30 minutes, ↓ 57,8% at Day 6.
- Headache evolution ↓ 64,3% at day 3, ↓ 74,9% at Day 6.
- Sinus pain ↓ 65,4% at day 3, ↓ 76,8% at Day 6.
- Improves nasal discharge in cases of rhinitis.
- Overall improves the severity of rhinosinusitis and reduces the need for antibiotic therapy.

Shrivastava & al. 2017 — J. Clinical Respiratory Diseases and Care

## CLAIMS

- Fast-acting nasal decongestion — starts in 30 minutes
- Rapid relief of sinus pain — within 1 day
- Clears mucus fast, then reduces runny nose

Symptom reduction over time (%)



- Up to ~95% symptom reduction by Week 3
- Fewer patients needed antibiotics

Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand

# NESOSPRAY KIDS

Treatment of rhinitis, rhinosinusitis and nasopharyngitis in children

3+



Example of a product visual

## COMPOSITION

Filmogenic glycerol, Rhinocyanidin-E (from plant-based ingredients).

## PRESENTATION

15 ml nasal spray.

## DESCRIPTION

NESOSPRAY KIDS is a Class IIa medical device indicated for the treatment of rhinosinusitis, rhinitis and nasopharyngitis in children. Based on natural polymers, it forms a filmogen, stable, osmotic film on the nasal mucosa. The mechanical cleaning action generated by osmosis helps to detach surface contaminants and to decongest the nasal passages. MDR approved and supported by clinical studies.

1. Protects from contaminants & particles

2. Flushes out contaminants & mucus

3. Breaks the inflammation cycle

## CLINICAL STUDIES

The double-blind clinical study showed significant results in children within 3 days of use; no adverse effects were reported.

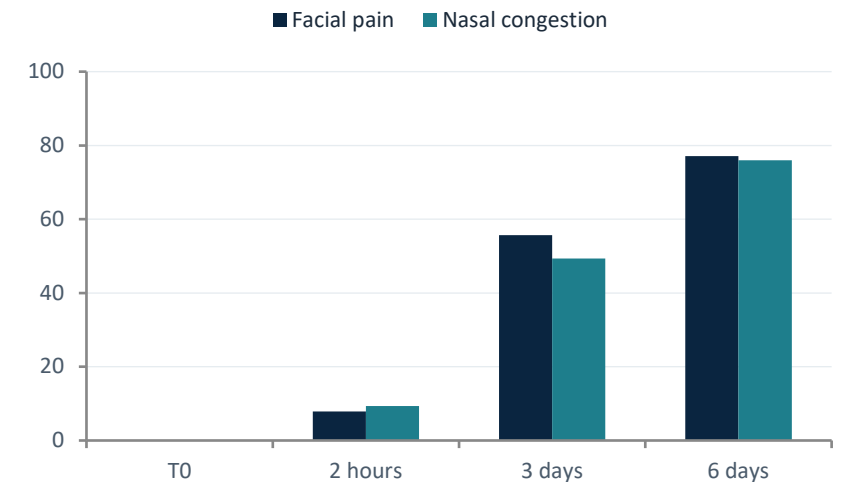
- Nasal symptoms ↓ 49.3% (Nesopray) vs 9.3% (saline) by Day 3; ↓ 98% by Day 15.
- Sleep quality ↑ 58.4% vs 16.1% (saline) by Day 3; 100% of children had no sleep complaints by Day 15.
- Facial pain ↓ 55.7% vs 24.3% (saline) by Day 3; ↓ 97.1% by Day 15.

Shrivastava & al. 2022 — Journal of Clinical-Investigation

## CLAIMS

- Significant reduction in nasal congestion
- Improved sleep quality
- Reduces facial pain

Symptom reduction over time (%)



- Improvement in rhinitis symptoms
- Reduces the need for antibiotic therapy

Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand



Example of a product visual

## COMPOSITION

Filmogenic glycerol, Migcyanidin (from plant-based extracts).

## PRESENTATION

15 ml nasal spray.

## DESCRIPTION

MIGSPRAY is a Class IIa medical device designed for the preventive treatment of episodic migraine. Its innovative technology, based on natural film-forming polymers, acts locally through a purely mechanical mode of action. By modulating the nasal microenvironment and reducing peripheral trigeminal stimulation, MIGSPRAY helps to decrease the frequency and intensity of migraine attacks. Clinically proven and MDR-certified, MIGSPRAY offers a safe, drug-free, and effective solution for long-term migraine prevention.

1. Acts on migraine pathways

2. Protects against migraine triggers

3. Breaks the migraine cycle

## CLINICAL STUDIES

Three independent clinical studies have demonstrated the efficacy and safety of MIGSPRAY in the preventive treatment of episodic migraine. Results show a significant reduction in both the frequency and intensity of migraine attacks, with no serious or systemic adverse events reported. MIGSPRAY can be used in combination with the patient's usual preventive or acute therapies.

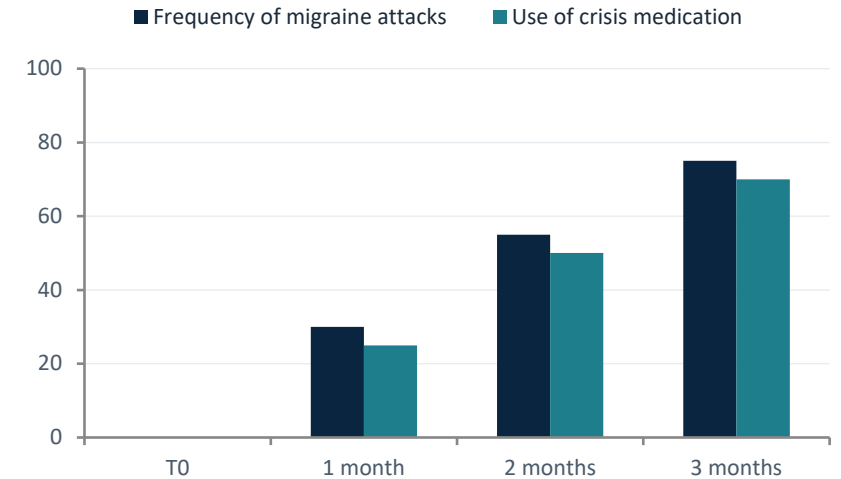
- Significant reduction in frequency of migraine attacks (3 independent clinical studies).
- Significant reduction in the intensity of migraine attacks.
- No serious or systemic adverse events reported.
- Combinable with the patient's usual preventive or acute therapies.

Shrivastava & al. 2023 — Journal of Clinical-Investigation

## CLAIMS

- Reduces migraine frequency
- Reduces migraine intensity
- Shortens migraine duration

Reduction over treatment period (%)



- Reduces migraine days by over 60% in children
- Improves daily life and productivity
- Improves quality of life

Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand



Example of a product visual

## COMPOSITION

Filmogenic glycerol, honey, Mucocyanidin (from plant-based ingredients).

## PRESENTATION

20 ml throat spray.

## DESCRIPTION

OROSOL is a Class IIa medical device indicated for the treatment of oral mucositis induced by radiotherapy or chemotherapy. Based on natural polymers, it forms a filmogen, stable, and non-irritating protective barrier in the oral cavity. MDR approved and supported by clinical studies.

1. Coats and protects damaged oral mucosa

2. Soothes quickly pain, irritation & dryness

3. Supports mucosal recovery cycle

## CLINICAL STUDIES

Several randomised placebo-controlled clinical trials have been conducted in adult and paediatric patients undergoing radiotherapy or chemotherapy.

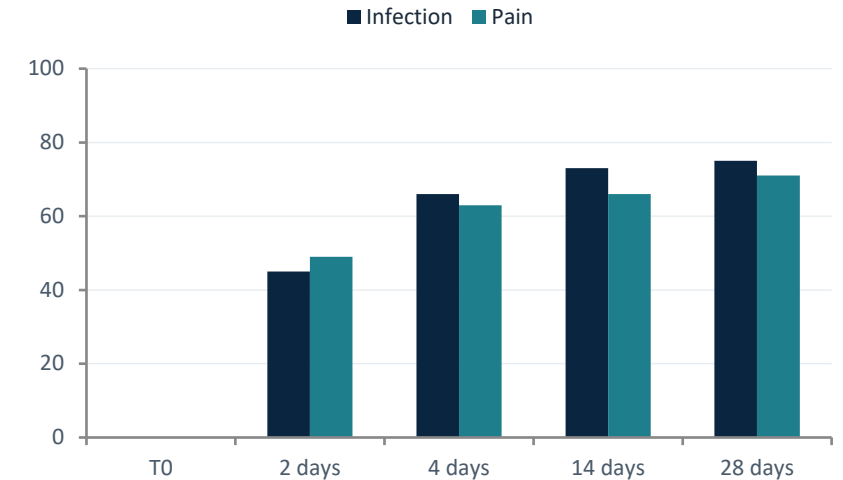
- Mucositis grade ↓ 23% at Day 2; ↓ 41% at Day 4.
- Pain sensation ↓ 34% within 30 minutes; ↓ 57% at Day 3.
- Burning sensation ↓ 41% at Day 1; ↓ 66% at Day 4.
- Infection (bacterial/fungal) ↓ 45% at Day 2; ↓ 66% at Day 4.
- New ulcer formation ↓ 18% at Day 3; ↓ 23% at Day 4.

Shrivastava & al. 2013 — Journal of Cancer Research and Treatment

## CLAIMS

- Fast relief from oral pain in just 30 minutes
- Soothes mouth ulcers and redness
- Improves eating comfort in just 4 days

Reduction over time (%)



- Reduces mucositis severity from Day 7
- Significant pain reduction from Day 2
- Soothes burning sensation from the first use

Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand



Example of a product visual

## COMPOSITION

Filmogenic glycerol, xanthan gum, honey, Herpcyanadol (from plant-based ingredients).

## PRESENTATION

6 ml tube.

## DESCRIPTION

ORALHERP is a Class IIa medical device indicated for the treatment of labial herpes lesions. Based on natural polymers, it forms an osmotic, stable, and non-irritating film on the affected area, protecting the lesion from further contamination and promoting healing. MDR approved and supported by clinical studies.

1. Creates an Optimal Healing Environment

2. Protect from contaminants

3. Soothes & Protects Quickly

## CLINICAL STUDIES

The placebo-controlled clinical study showed significant results within the first two hours of use.

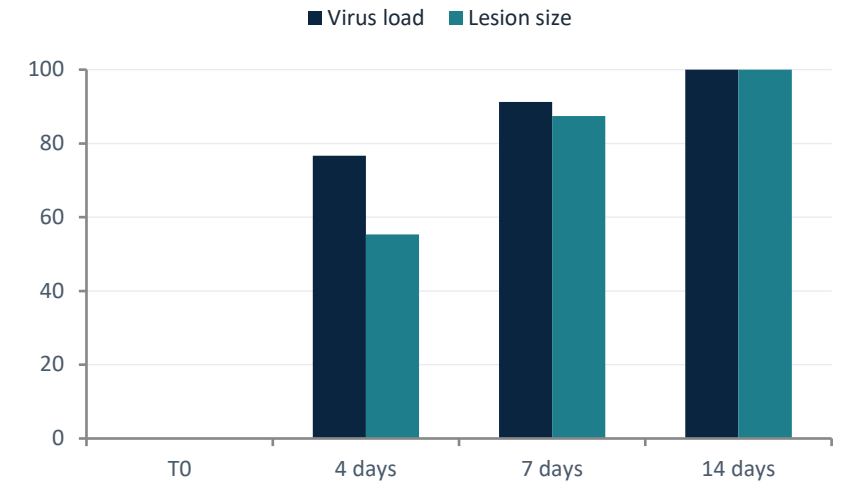
- Virus-infected cells ↓ 38% at 2h; ↓ 52% at Day 4.
- Lesion area ↓ 55.3% at Day 4; ↓ 87.4% at Day 7.
- Virus density ↓ 76.7% at Day 4; ↓ 91.2% at Day 7.
- Reduction in pain, burning and irritation; no adverse effects reported.

Shrivastava & al. 2013 — International Journal of Biological & Pharmaceutical Research

## CLAIMS

- Reduces herpes virus load from the first application
- Eliminates 99% of herpes virus in 14 days
- Accelerates healing of cold sores

Reduction over time (%)



- Relieves pain, burning and itching fast
- Soothes discomfort within hours

Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand



Example of a product visual

## COMPOSITION

Filmogenic glycerol, xanthan gum, honey, Proteocyanidin (from plant-based ingredients).

## PRESENTATION

10 ml tube.

## DESCRIPTION

OROHEAL is a Class IIa medical device indicated for the treatment of oral ulcers. Based on natural polymers, it forms an osmotic, stable, and non-irritating film over the ulcer, providing quick relief. MDR approved and supported by clinical studies.

1. Creates an Optimal Healing Environment

2. Protect from irritants

3. Soothes & Protects Quickly

## CLINICAL STUDIES

A clinical study was conducted on adult and paediatric populations and showed rapid results across all symptoms.

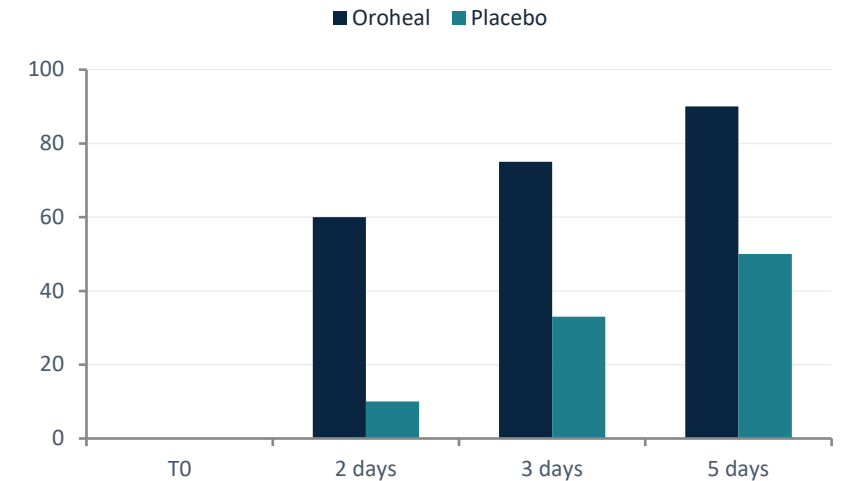
- Ulcer healing 60% vs 10% (placebo) on Day 2; 75% vs 33% on Day 3.
- 84% of patients gave Oroheal a good or excellent overall rating.

Shrivastava & al. 2006 — International Journal of Clinical Drug Investigation

## CLAIMS

- 75% of users healed within 3 days
- Faster relief than common treatments

Ulcer healing — Oroheal vs placebo (%)



- Soothes and relieves discomfort quickly
- Easy and pleasant to use

Class IIa medical device

MDR 2017/745

CE 0459

ISO 13485

Ready-to-market under your brand

# | F.A.Q ?

## **Who is the legal manufacturer ?**

The legal manufacturer is always VitroBio. Its name and address appear on the packaging. The marketing company is indicated as the "distributor".

## **Do you have several formulas for different therapeutic indications ?**

Yes, for some indications we have 2 to 3 possible formulations.

## **Which ISO standard do you follow ?**

We are ISO 13485 certified for medical devices.

## **Are all products MDR 2017-745 certified in accordance with the new European regulation ?**

Yes, all products offered are MDR certified by our notified body, GMED.

## **Do you provide full regulatory documentation?**

We offer a turnkey solution with all documentation necessary for registration. Our regulatory team provides full support throughout the process and answers all questions.

## **What can the distributor do with the product?**

The distributor has full control over the product's market positioning. They can select the brand name, design the packaging, and determine which claims to highlight. This flexibility enables them to align the product perfectly with their brand identity and target market.

## **Are there any general claims for the products?**

Yes, in addition to specific clinical claims, the products benefit from a range of general claims that enhance their market positioning. These include "Made in France," "Clinically Proven Efficacy," "Ingredients of Natural Origin," and other value-driven statements that strengthen the product's positioning and credibility.

## **Can claims be added?**

Yes, additional claims can be included, provided they are supported by clinical evidence. Any new claim must be substantiated by data from our clinical studies or validated through our manufacturing processes. We're open to discussing new claim opportunities that align with our existing scientific documentation.

## **Are the products protected by a patent ?**

Our patent covers the technological innovation based on polymeric glycerol. It therefore covers all our products. The patent license is exclusively held by VitroBio, although our distributors indirectly benefit from the patent protection when marketing our products.

## **What are the minimum order volumes ?**

Total annual order volumes are contractually defined, generally over 3 years. The minimum batch size order is set at 20,000 units (minimum quantity to enable the production line to manufacture).

## **What is your production capacity ?**

We have 2 production lines. Each line has a capacity of around 25,000 products per day.

## **What shipping incoterm do you use?**

We deliver on an EXWORK basis. The distributor takes care of transport.



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[client@vitrobio.com](mailto:client@vitrobio.com)



VITROBIO

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