

HP-Betadex Nasal Spray | BDNS

Preservative-free Nasal Spray
with HP-Betadex

Bridging the Gap Between Saline Sprays and
Pharmacological Nasal Therapy



URSATEC
WHEN PRESERVATIVE FREE MATTERS®

aquilon
pharma

INTRODUCTION | HP-Betadex Nasal Spray

Bridging the Gap Between Saline Sprays and Pharmacological Nasal Therapy

*To be classified as a Medical Device
Class IIa under (EU) 2017/745 (MDR)*



For patients with NASAL DISCOMFORT related to:

- ✓ Rhinitis (Common Cold)*
- ✓ Allergic Rhinitis*
- ✓ Rhinosinusitis*

* including associated nasal dryness



Supporting nasal care through a physical mode of action:

- ✓ Natural decongestant
- ✓ Moisturizing & cleaning of nasal cavity
- ✓ Improvement of mucociliary clearance
- ✓ Reduces the duration and severity of a viral infection, which often is the cause for a common cold
- ✓ Supports in:
 - ✓ Alleviation of inflammatory events
 - ✓ Restoration / regeneration of nasal mucosa

- ✓ Availability expected in 1st half of 2027.
- ✓ Patent protected until 2040.

WHAT IS HP-BETADEX NASAL SPRAY?



HP-Betadex Nasal Spray is a preservative-free medical device that supports nasal mucosal care through a physical, non-pharmacological mode of action as an alternative in nasal discomfort management.

Formulation

Water,
Sodium Chloride,
HP-Betadex

Device

URSATEC 3K®
non-airless
nasal spray pump

Action

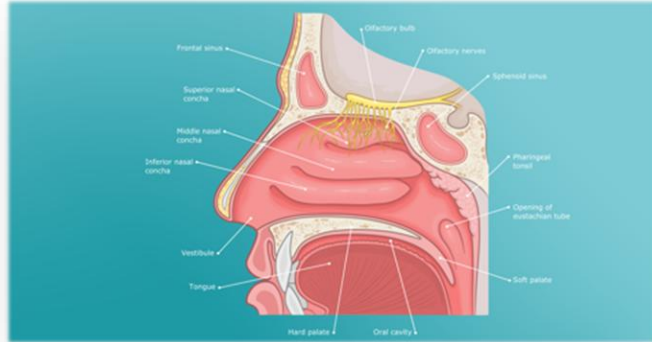
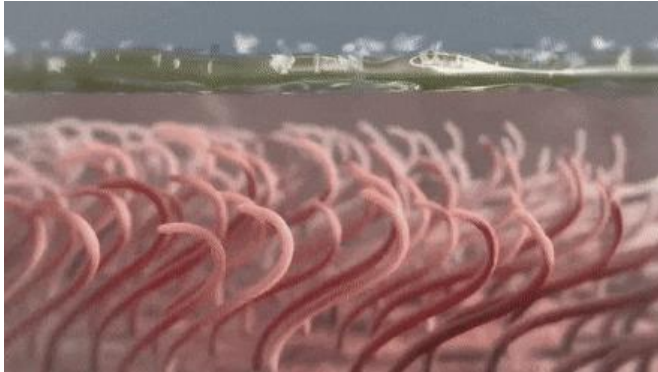
Physical,
non-pharmacological*
mode of action

*A cyclic oligosaccharide, based on physico-chemical properties and water-binding ability of HP-Betadex, supports the mucosal care concept.

Positioning

A differentiated step in nasal care between basic saline sprays and pharmacological therapies such as intranasal corticosteroids, antihistamines, and decongestants.

WHY NASAL MUCOSA MATTERS?



The nasal cavity is lined with mucus-producing cells and cilia.

Mucus helps capture particles and allergens.

Cilia help move mucus toward the nasopharynx, supporting natural nasal clearance.

A nasal care product should support this environment without adding preservative burden.

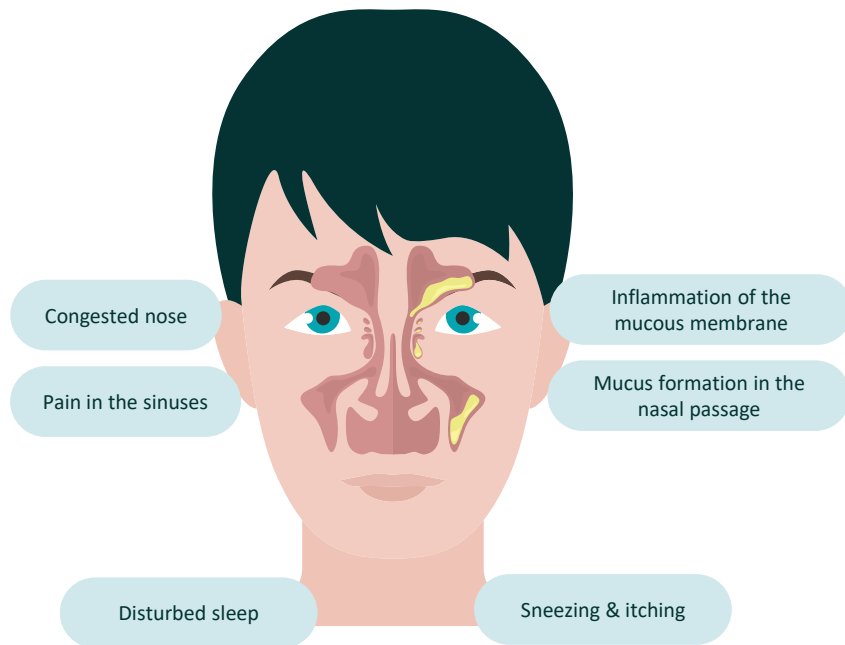
NASAL DISCOMFORT | MORE THAN A CONGESTED NOSE

Nasal discomfort may be associated with:

- Congested nose
- Increased mucus formation
- Irritated nasal mucosa
- Sinus pressure or pain
- Sneezing and itching
- Disturbed sleep

Common triggers include allergic and non-allergic rhinitis, upper respiratory tract infections, and environmental irritants.

A nasal care product should support the nasal mucosa while being gentle enough for repeated use.



CLOSING THE GAP IN NASAL CARE

A differentiated non-pharmacological step between saline sprays and pharmacological therapy.

Basic Saline Sprays

- Cleansing
- Rinsing
- Hygiene-focused
- Limited differentiation

HP-Betadex



- Preservative-free
- Medical Device with physical mode of action
- Non-pharmacological
- Supports nasal mucosa

Pharmacological Nasal Therapy

- Steroids
- Antihistamines
- Decongestants
- Drug-based treatment

HP-Betadex Nasal Spray bridges the gap between saline sprays and pharmacological therapy.

WHY HP-Betadex?

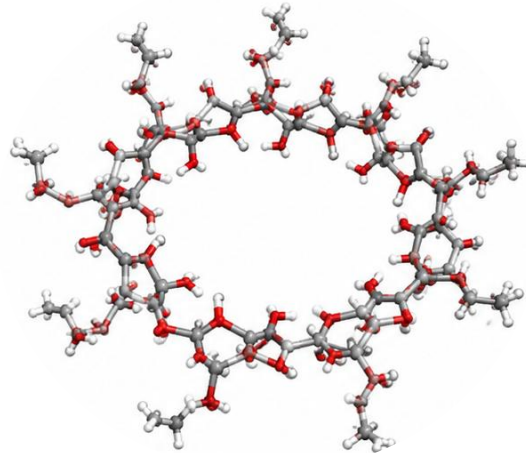
HP-Betadex combines well-established safety with unique physico-chemical properties to support nasal mucosal care in a preservative-free, non-pharmacological medical device.

1 Well-Established Excipient

- ✓ Cyclic oligosaccharide
- ✓ Widely used excipient
- ✓ Biocompatible and well tolerated

3 Water-Binding Ability

- ✓ Supports hydration
- ✓ Supports the nasal mucosal environment
- ✓ Has a natural decongestion effect



Hydroxypropyl β -Cyclodextrin (HP- β -CD)

2 Physical Mode of Action

- ✓ To be classified as Class IIa Medical Device (EU MDR) // Q2 2027
- ✓ Physical mode of action
- ✓ No pharmacological active ingredient

4 Differentiation from Saline

- ✓ Beyond basic cleansing
- ✓ Supports nasal mucosa
- ✓ Creates a differentiated product positioning

HP-Betadex differentiates the product from basic saline sprays while maintaining a non-pharmacological Class IIa medical device profile.

PROVEN STABILITY UNDER ICH CONDITIONS

All critical quality attributes remained within specification throughout long-term and accelerated stability studies.

LONG TERM // 25°C / 60% RH

✓ 30 months stable

ACCELERATED // 40°C / 75% RH

✓ 12 months stable

- ✓ Appearance & odour
- ✓ pH
- ✓ Osmolality
- ✓ Assay Sodium Chloride
- ✓ Identification & Assay HP-Betadex
- ✓ Uniformity of delivered mass
- ✓ Sterility

Questions?

Are you interested in receiving further information on our finished products? Please contact us directly!



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