pump up your performance

Nemera
DEVICES ARE KEY TO DRUG EFFICACY…

The intranasal route is widely used for both prescription and over-the-counter drugs. It is an attractive option for topical drugs (e.g. nasal decongestants or nasal steroids), as well as for systemic acting drugs (anti-migraine medication, hormones, etc.), boasts a rapid onset of action and it is very convenient.

Moreover, treatments via the nasal route are self-administered and therefore nasal delivery systems have a positive impact on compliance.

...with Nemera delivery devices for ear, nose, throat formulations

Nemera offers standard delivery devices for nasal, buccal and auricular routes for both OTC and prescription drugs. They are recognized and valued by patients and pharmaceutical companies alike. We guarantee precision and dose consistency, to ensure an optimal treatment. The development of the new Nemera multidose nasal spray, Advancia®, illustrates perfectly our patient-oriented innovation process. The new technology pump provides outstanding performance responding to increasing regulatory requirements for nasal sprays.

Standard devices portfolio
- Metered pumps
- Continuous valves

Customized solutions

Industrialization and manufacturing of customers’ solutions
Quality for patients

Accurate dosing and ergonomics contribute to patients’ adherence. That is why at Nemera, we put patients first when designing, developing and manufacturing drug delivery devices. Nemera proprietary products benefit from the utmost care because we know how critical they are for patients’ health.

With over 50 years of experience in packaging development and industrialization, Nemera provides customers with a thorough spray expertise, and ensures the highest standards of product performance.

We are committed to providing excellence in the quality of our products and services:

- Full traceability, 100% in-line controls
- ISO 9001, ISO 13485 and ISO 15378 certification
- Production according to GMP
- Manufacturing in ISO CLASS 8 clean rooms
- DMF available

OUR RANGE

HOW TO CHOOSE FROM OUR SOLUTIONS?

Nemera proposes a comprehensive range of non-pressurized (pumps) and pressurized (valves) dispensing systems, compatible with a wide choice of actuators suitable for each delivery route (nasal, buccal, auricular, etc.).

Millions of people suffering from allergic rhinitis rely everyday on nasal sprays manufactured by Nemera.

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Millions of people suffering from allergic rhinitis rely everyday on nasal sprays manufactured by Nemera.

<table>
<thead>
<tr>
<th>Doses (μl)</th>
<th>Pumps</th>
<th>Valves</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Advancia®*</td>
<td>SP270+</td>
</tr>
<tr>
<td>50</td>
<td>70</td>
<td>80</td>
</tr>
<tr>
<td>100</td>
<td>140</td>
<td></td>
</tr>
<tr>
<td>140*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Crimp-On

FEA 13 mm

FEA 20 mm

Screw-On

DIN 18/10

DIN 18/13

GCMI 18/415

GCMI 20/400

GCMI 20/410

Snap-On

FEA 20 mm

*standard (industrial)  *pilot

*in development

FITMENTS

Crimp-on  Screw-on  Snap-on

We have qualified a number of rigid bottles compatible with our standard range of pumps, for a full solution.

Please consult us for recommendation of compatible bottles and introduction to bottle suppliers.
Advancia® is the high performing metering pump platform that patients can count on. With accurate dosing, patients can be confident that each dose is fully delivered.

Advancia® offers a new alternative to improve treatment compliance in an increasingly demanding nasal spray market. Designed to be a step ahead of today’s pumps, Advancia® is based on a new system combining user-independence and preservative-free features in one single system. Moreover, its closing tip prevents clogging with formulations prone to crystallization.

**Key product features**
- **User-independence**
- Excellent **dose consistency**
- Long **prime retention**
- Mechanical **closing tip** to prevent clogging issues
- **No metal part** in contact with the formulation
- Plastic components compliant with **EP-USP-FDA regulations**
- **DMF** available
- **One-step snap-on** process to boost productivity on filling lines
- **Preservative-free** version in development

**As a platform, Advancia® offers different options (2 pump engines, 2 fitments, 3 doses) suitable for:**
- Lifecycle management of off-patent allergic rhinitis products and OTC decongestants
- New combination treatments that target nasal allergies (e.g. steroids + antihistamines)
- Pipeline allergy molecules
- New drugs in development through the nasal route

<table>
<thead>
<tr>
<th>Fitment</th>
<th>Advancia® Std</th>
<th>Advancia® PF*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Crimp-on 20 mm</td>
<td>Snap-on 20 mm</td>
</tr>
<tr>
<td></td>
<td>Snap-on 20 mm*</td>
<td></td>
</tr>
<tr>
<td>Doses (µl)</td>
<td>50, 100, 140*</td>
<td>50, 100, 140*</td>
</tr>
<tr>
<td>Raw materials in contact with the formulation</td>
<td>PE, PP, gasket raw materials, silicone</td>
<td>PE, PP, silicone</td>
</tr>
<tr>
<td>Nasal actuators</td>
<td>Crimp-on</td>
<td>Snap-on</td>
</tr>
</tbody>
</table>

* in development
The patients’ voice is the key driver of Nemera product development. Patient insights and human factor studies are at the heart of our Innovation process.

We conduct user-studies to make sure our products respond to patients’ needs, and to benchmark Nemera delivery systems versus competition.

Two user studies were performed with Advancia® in 2011 and 2013 with 30 patients, including children, adults and seniors, with a double objective:

• Demonstrate the user-independence feature of Advancia®
• Benchmark Advancia® vs. competition on dose consistency

RESULTS

Advancia® is the best performing pump, both on dose accuracy and reproducibility, independently of the user.

Users also highlighted Advancia®’s integrated Snap-on design, well-suited to today’s on-the-go lifestyle.
The New optimized SP270+ pump is the result of continuous improvements to the SP270 pump platform. The SP270 pump platform has been used worldwide for drug delivery for more than 20 years and has a successful track record of large scale GMP production. We continue to optimize it to respond to patients’ needs and customers’ requirements.

The extensive range of actuators available makes these pumps easily adaptable for nasal, buccal and auricular liquid formulations, for the convenient and safe delivery of drugs to patients of all ages. The SP270+ is ideal for delivering liquid solutions and suspensions.

Key product features

- Good priming and dose consistency through life
- Built-in pre-compression provides a fine and reproducible spray
- Materials compliant with FDA and EU regulations
- DMF available
- Wide range of doses (50 μl to 140 μl)
- Broad range of actuators
- Full polyolefins version upon request

BIOEQUIVALENCE

Nemera has established a Device Equivalence Program in order to respond to market enquiries in terms of nasal spray equivalence and second-sourcing needs.

Nemera proposes appropriate delivery systems to companies wishing to save time in their nasal spray development programs.

Please contact us for any request.
SP3

The SP3, oversized pharmacy format, is produced to the same standards as the SP270+ pump, and gives a comparable performance. All actuators for nasal, buccal, auricular and other applications suitable for SP270+ platform are also compatible with SP3. SP3 is ideal for delivering liquid solutions and suspensions, requiring higher doses than SP270+.

<table>
<thead>
<tr>
<th>SP270+</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stated doses (μl)</strong></td>
<td>50, 70, 80, 90, 100, 130, 140</td>
</tr>
<tr>
<td><strong>Fitment</strong></td>
<td>Crimp: FEA 20 mm</td>
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<tr>
<td></td>
<td>Snap: FEA 20 mm</td>
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<tr>
<td></td>
<td>Screw: DIN 18/10 - DIN 18/13</td>
</tr>
<tr>
<td></td>
<td>GCMI 18/415 - GCMI 20/400 - GCMI 20/410</td>
</tr>
<tr>
<td><strong>Raw materials in contact with the formulation</strong></td>
<td>LDPE, PP, gasket raw materials, POM, stainless steel</td>
</tr>
</tbody>
</table>

Nominal dose with distilled water may differ slightly from the stated dose.

<table>
<thead>
<tr>
<th>SP3</th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Stated doses (μl)</strong></td>
<td>180, 200, 230</td>
</tr>
<tr>
<td><strong>Fitment</strong></td>
<td>Crimp: FEA 20 mm</td>
</tr>
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<td></td>
<td>Snap: FEA 20 mm</td>
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Nominal dose with distilled water may differ slightly from the stated dose.
# ACTUATORS

## NASAL
The right shape and size for your local or systemic nasal sprays.

<table>
<thead>
<tr>
<th>Fitments</th>
<th>4345</th>
<th>2371 - 9130</th>
<th>5733</th>
<th>3959</th>
<th>3960</th>
<th>4095</th>
<th>8238</th>
<th>8841</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference</td>
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<tr>
<td>Pediatric use</td>
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<td></td>
</tr>
<tr>
<td>CRIMP-ON</td>
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</tr>
<tr>
<td>SNAP-ON</td>
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<td></td>
</tr>
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</tr>
</tbody>
</table>

## Accessories
- Nasal cap #1033
- Blue safety clip #1060

## BUCCAL
Different arms lengths for fighting buccal-pharyngeal infection.

<table>
<thead>
<tr>
<th>Fitments</th>
<th>9180</th>
<th>8940</th>
<th>4234</th>
<th>9994</th>
<th>5860</th>
<th>4325</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRIMP-ON</td>
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<td></td>
<td></td>
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<tr>
<td>SNAP-ON</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>SCREW-ON</td>
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</tbody>
</table>
AURICULAR
The right combination of actuators for ear treatment.

<table>
<thead>
<tr>
<th>Fitments</th>
<th>Reference</th>
<th>CRIMP-ON</th>
<th>SNAP-ON</th>
<th>SCREW-ON</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5860</td>
<td>-</td>
<td>-</td>
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<tr>
<td></td>
<td>9180</td>
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<tr>
<td></td>
<td>4234</td>
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</tr>
</tbody>
</table>

Accessories

OTHERS
Other actuators suitable for buccal, dental applications.

<table>
<thead>
<tr>
<th>Fitments</th>
<th>Reference</th>
<th>9590</th>
<th>5200 (straight or folded)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CRIMP-ON</td>
<td></td>
<td></td>
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<tr>
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</tr>
<tr>
<td></td>
<td>SCREW-ON</td>
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<td></td>
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</tbody>
</table>
CONTINUOUS VALVES

The pressurized delivery solution with continuous valves

**CV20**
for liquid formulation

**Valve 6668**
for viscous products such as gels

**Valve 6685**
for pharmaceutical powders

<table>
<thead>
<tr>
<th>References</th>
<th>CV20</th>
<th>6668</th>
<th>6685</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fitment</strong></td>
<td></td>
<td></td>
<td>FEA 20 mm</td>
</tr>
<tr>
<td>Raw materials in contact with the formulation</td>
<td>PE, POM, gasket raw materials, stainless steel</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**KEY ADVANTAGES**

- continuous valve with a neutral propellant agent (nitrogen) or liquid gases
- isolates the active ingredient from the aluminium ferrule
- fitting (FEA 20 mm)

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ACTUATORS

NASAL

The right shape and size for your local or systemic nasal sprays.

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BUCCAL

Different arms lengths for fighting buccal-pharyngeal infection.

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<tr>
<td>cap 662</td>
<td>918</td>
<td></td>
</tr>
<tr>
<td>918</td>
<td>894</td>
<td></td>
</tr>
<tr>
<td>4229</td>
<td>8400</td>
<td>585</td>
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AURICULAR

The right combination of actuators for ear treatment.

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<tr>
<td>585</td>
<td>AA4238</td>
<td>AA8400</td>
</tr>
<tr>
<td>4229</td>
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<td></td>
</tr>
</tbody>
</table>
SERVICES

Nemera supports customers according to their project needs:

- Selection and supply of delivery systems (pumps or valves, actuators and caps) from initial testing purposes to stability studies or clinical trials
- Dip tube adaptation to the selected container
- Recommendation of compatible bottle and introduction to bottle suppliers

SAMPLING

Regulatory support at each stage of development to help obtaining market approval for your drug product

- US-DMF Type III available for our pumps
- Raw material expertise
  - pharma compliance for materials in contact with the formulation
  - extractable reports upon customer request

LABORATORY

Our highly qualified team has an extensive knowledge of pharmaceutical requirements to support your projects. Our laboratory is at the cutting edge of technology and is able to perform a wide range of tests related to the device performance with customer formulations on nasal, buccal and auricular sprays.

The following tests can be performed by our specialists:

**Pump performance**
- dose accuracy
- strokes to prime/re-prime
- weight loss
- gasket swelling
- actuation/assembly force
- leakage test
- ageing

**Spray characterization**
- spray pattern
- plume geometry
- droplet size distribution

**Spray pattern analysis:**
- determination of the spray impact

**Plume geometry analysis:**
- determination of the spray angle

OTHERS

Regulatory support at each stage of development to help obtaining market approval for your drug product

- US-DMF Type III available for our pumps
- Raw material expertise
  - pharma compliance for materials in contact with the formulation
  - extractable reports upon customer request
Nemera is a world leader in the design, development and manufacturing of drug delivery solutions.

50+
OVER 50
ENGINEERS IN DEVELOPMENT

30000+
OVER 30,000
SQM OF CLEAN ROOM MANUFACTURING

47
SALES IN
47 COUNTRIES

750
OVER 750 MILLION
DEVICES PRODUCED YEARLY

1300+
OVER 1300
EMPLOYEES

4 PLANTS IN EUROPE & THE USA

• Neuenburg, Germany
• La Verpillière, France
• Le Tréport, France
• Buffalo Grove, IL, USA

OUR PORTFOLIO

• ear, nose, throat
• pulmonary
• dermal/transdermal
• parenteral
• ophthalmic

Nemera

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information@nemera.net