

SKIN DRUG DELIVERY:

DERMAL, TRANSDERMAL & MICRONEEDLES



Nemera

ENSURING FORMULATION PROTECTION AND PATIENT CARE WITH AIRLESS DISPENSERS

In this article, Audrey Chandra, Category Project Manager, Manuela Basso, Communications Manager, and Raphaële Audibert, Global Category Manager, Inhalation and Dermal, all at Nemera, consider Nemera's holistic approach to dermal drug delivery, explaining why airless technology is important for dermal pharmaceutical applications.

INTRODUCTION

Dermal application is a non-invasive way to administer solutions, lotions, gels or creams on the skin. It is used as a drug delivery path to target different parts of the body.

The first, and most common, target is the upper layers of the skin itself to treat dermatological conditions such as acne, atopic dermatitis or psoriasis. Acne, as an example, is estimated to affect 9.4% of the global population, making it the eighth most prevalent disease worldwide, according to the British Association of Dermatologists.

The second target is the bloodstream, known as "transdermal systemic delivery", whereby gels or creams are absorbed and circulated into the whole body through the bloodstream. The main examples here are hormone replacement therapy (HRT) for women with menopausal symptoms or men with hypogonadism.

The third target is the underlying tissues below the skin layers for the application of anti-inflammatory treatments directly to the source of the problem, most commonly aching knee, elbow and shoulder joints. Here, the drug is absorbed through the skin into the muscles and tendons below.

DERMAL DELIVERY DEVICES FOR PHARMA APPLICATIONS

Both cosmetics and dermal pharmaceuticals use the skin as their point of access, but there is a world of difference in the way they are regulated and manufactured.

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Very few can fulfil these requirements. They can be identified by their compliance with regulatory standards specific to packaging of medicinal products and medical devices.

This is essential to ensure that both the formulation and its container are safe and easy to use for patients. Some dermal delivery devices are airless, which ensures the formulation is not in contact with air.

With some of the treatments, the formulations they contain are very sensitive and need to be perfectly protected to remain stable. When you press down on the pump of, for example, a soap dispenser, you have air that enters the bottle when the product is dispensed, but that does not happen with airless devices. This allows patients to use the device in any position, and allows the pharma company to avoid overfilling, as most of the formulation is delivered from the device.



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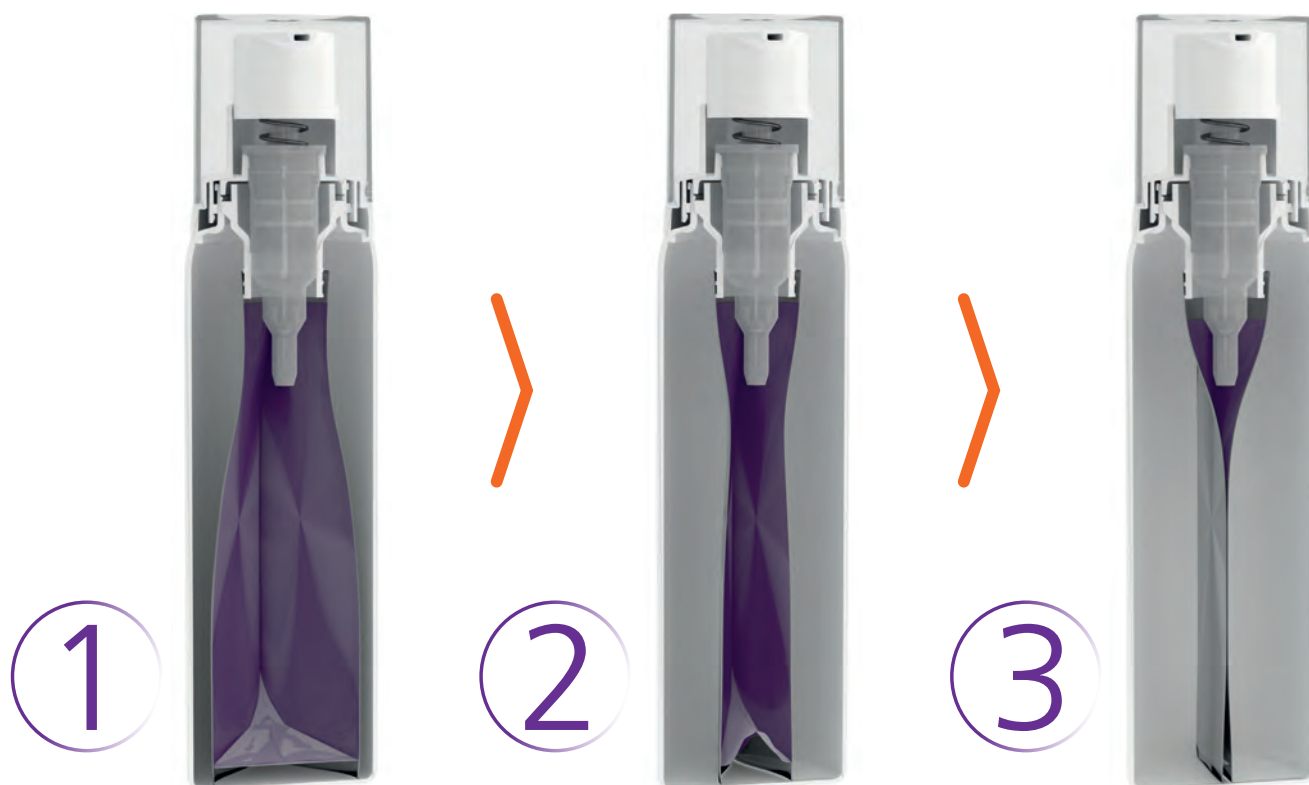


Figure 1: Sof'Bag® pouch collapsing during product life.

NEMERA'S LONG-STANDING EXPERIENCE IN DERMAL

Nemera has been working in the dermal field for the past two decades, producing airless devices used by some of the biggest pharmaceutical companies in the world, and is a leader in the systemic transdermal gel and cream market.

The company provides an end-to-end service, helping customers navigate their device strategy for both novel and platform solutions, including technical support for drug filling, and the submission of registration dossiers to the appropriate regulatory authorities.

This holistic approach and integrated front-to-end services enable Nemera to innovate within every development phase of its products and ultimately deliver solutions to meet patients' needs.

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Compliant with the most demanding regulatory standards specific to packaging of medicinal products and medical devices, Nemera's devices are well suited to topical or systemic drugs such as local anaesthetics, anti-inflammatories, hormones, antibiotics, antifungals or counterirritants for the skin.

The first treatment launched with a Nemera device was for cold sores and today millions of patients rely on its precise delivery systems for a wide range of topical and systemic conditions in the dermal drug delivery field alone.

Nemera focuses on addressing patients' needs by developing and producing high-end devices as well as on giving the pharmaceutical companies all the technical support they might need along the way.

The airless device Sof'Bag® was developed in the same spirit.

SOF'BAG®: THE AIRLESS POUCH-IN-BOTTLE TECHNOLOGY FOR SENSITIVE FORMULATIONS

Sof'Bag® was designed to ensure that patients receive a consistent treatment as a result of precise and reliable dosing, which is especially critical when applying formulations for systemic treatments.

It is an airless packaging solution for prescription (Rx) and over-the-counter (OTC) formulations for dermal and transdermal applications composed of an aluminium-based collapsible pouch encased

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inside a rigid bottle surrounded by a metered pump dispenser (SP943).

Each actuation delivers a precise metered dose of formulation, which is dispensed out of the pouch as shown in Figure 1. No air enters into the pouch during this process.

Sof'Bag® is suitable for solutions, lotions, gels and creams, even the most sensitive ones. Thanks to its multi-layer, collapsible, aluminium pouch technology, formulations are highly protected from oxidation, light and moisture.

With 360° delivery due to its airless property, the Sof'Bag® makes treatment administration more convenient for patients. In addition, very little of the product is wasted – more than 95% of the contents of this "pouch-in-a-bottle" can be extracted.



Figure 2: A patient using Sof'Bag®.

Sof'Bag® is also fully customisable and it is possible to modify cap and bottle colours, shapes and sizes, or to add new functions (dose counter, electronics features, etc.) (Figure 2).

SOFAIRLESS XS: THE AIRLESS PISTON TECHNOLOGY

Sof'Airless XS is the solution for trial sizes or local treatments with very little skin surface to cover: a protective mini-airless system for small dose applications and sampling.

Sof'Airless XS targets Rx and OTC dermal gels and creams. It is compact and portable (2 mL size) and can be used in any position. The airless piston technology allows the formulation to be dispensed out of a rising piston upon pump actuation.

Sof'Airless XS is already used for the treatment of cold sores (Figure 3).

ABOUT THE COMPANY

As a world-leading drug device combination solutions specialist, Nemera's purpose of putting patients first enables it to design



Figure 3: A patient using Sof'Airless XS.

and manufacture devices that maximise treatment efficacy.

Nemera is a truly holistic partner that helps its customers succeed in the sprint to market. From early device strategy to state-

of-the-art manufacturing, the company is committed to the highest quality standards.

Agile and open-minded, Nemera works with its customers as colleagues, going the extra mile together to fulfil their mission.

ABOUT THE AUTHORS

Audrey Pamila Chandra is the Category Project Manager at Nemera. She joined Nemera in 2019. Ms Chandra graduated from the Faculty of Medicine Universitas Atma Jaya Indonesia and pursued her Master's degree in Strategy and Business Development at Toulouse School of Management, France. With her dual competence asset, she is in charge of providing strategic support for various targeted marketing projects and working on diverse content along with communication activities coordination.

Manuela Basso is an experienced communications professional, with a journalism and marketing background. Ms Basso holds a European Master in Management and specialised in International Marketing. She has been working at Nemera for six years, developing effective communications to support Nemera's overall vision and mission: to put patients first.

Raphaële Audibert holds a Biomedical Engineering degree from ISIFC (Besançon, France). Ms Audibert has worked in the medical device industry as a project manager for five years, where she led the development of a surgical instrument set for neurosurgery. Ms Audibert joined Nemera in 2016 as Category Manager for Inhalation and Dermal. Since then, she has helped identify the needs of tomorrow and in building the franchise strategies.

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Sof'Bag®

The airless solution for your sensitive formulations



we put
patients
First

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