

Lipidor AB

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Lipids fast-track active substances into the skin

Lipidor's AKVANO technology is a new delivery method for topical drugs and skin-care treatments that allows them to be applied as a spray.

Topical formulations for the delivery of pharmaceutical ingredients and skin-care treatments are traditionally in the form of ointments or creams, which contain lipids or lipid-like components. When these formulations are applied to the skin, the active ingredients must pass through at least one phase boundary in order to enter the lipid phase in the outermost layer of skin, the stratum corneum. For the ointment or cream to be effective, a thick layer must be rubbed into the skin to start the release of lipids.

Lipidor's AKVANO is a new proprietary drug delivery technology for topical treatment that takes a fundamentally different approach. Unlike ointments and creams, AKVANO water-free, sprayable formulations create a direct deposition of selected lipids and active ingredients on the surface of the skin (Fig. 1). The AKVANO principle enables efficient delivery of active ingredients and skin-barrier reinforcement, as well as good cosmetic qualities and improved convenience for patients. It is suitable for use on healthy, irritated, injured or diseased skin.

"AKVANO is a versatile technology platform that has applications in the topical dermatological field as well as nonpharmaceutical skin-care and cosmetic applications," said Anders Carlsson, Lipidor's CEO. "We are looking for partnerships and are offering licensing opportunities across the whole range of human applications on the skin and mucous membrane."

Carlsson cofounded Lipidor in 2009 in Stockholm after discovering the AKVANO principle. The company aims to develop, patent and commercialize formulation concepts and technologies based on lipids. Ongoing R&D activities are conducted at Stockholm University and the Karolinska Institutet Science Park in Stockholm.

Lipid layer

AKVANO is a liquid solution containing selected lipids that are dissolved in a volatile, water-free solvent mixture. The solvent evaporates when the formulation is sprayed onto the skin, leaving a thin lipid layer that adapts immediately to the skin's surface properties, enabling efficient delivery of a measured dose of the incorporated active pharmaceutical ingredient. "The lipid film that forms on the skin is crucial not only for the good cosmetic properties we achieve but also for direct deposition of the lipids and incorporated active ingredients that we would like to administer to the surface of the skin," said Carlsson.

The technology uses two different structural types of lipids, consisting of single or dual acyl chains, and the proportion of these in a specific AKVANO formulation can be altered to strengthen or loosen the barrier effect of the stratum

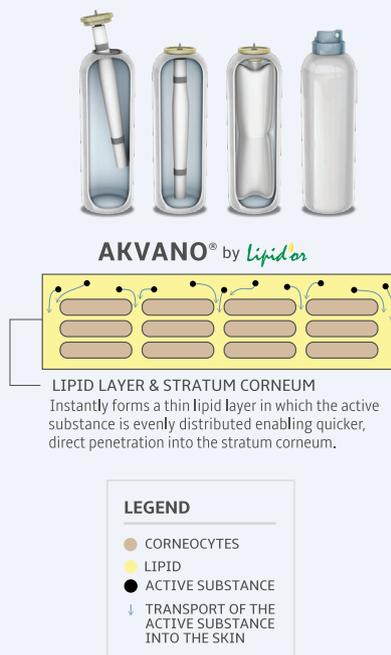


Figure 1: AKVANO is a new water-free, sprayable formulation based on lipids. Unlike with traditional ointments and creams, there are no phase boundaries between the active substance and lipids in the surface of the skin (stratum corneum) with AKVANO.

corneum. For example, tests have shown that formulations with a higher proportion of 'protecting' rather than 'penetrating' lipids can reduce the rate of transepidermal water loss. AKVANO is therefore particularly suitable for the delivery of drugs for dermatological diseases such as psoriasis and for the treatment of skin disorders such as atopic dermatitis, dry skin and eczema.

The convenient sprayable formulation has many advantages for patients in terms of good cosmetic qualities, including ease of use, rapid drying and a pleasant feeling on the skin. "Spraying is a particularly attractive way of administering the AKVANO solution because it is convenient when the skin has become irritated," said Carlsson. "There is no need to touch the skin after spraying—it dries within minutes and leaves a very thin film that is hardly visible."

Proof of concept

Lipidor is developing proprietary product concepts based on AKVANO formulations of active ingredients for which patent protection has expired. The lead product concept is a water-free, sprayable formulation of AKVANO and calcipotriol for treating mild-to-moderate psoriasis vulgaris (plaque psoriasis). Codedeveloped with

Cerbios-Pharma, this formulation addresses the problem of poor compliance with psoriasis therapy by offering efficient pharmaceutical delivery combined with good cosmetic qualities and improved patient convenience.

"The cosmetic quality of a topical formulation is a critical factor to enhance consistency and compliance," said Mona Stähle, professor of dermatology and venereology at the Karolinska Institutet. "The feedback I get from patients is very telling; greasy, sticky and unpleasant formulations tend to pile up in patients' homes, so this is where the AKVANO formulation may add true value."

A clinical phase 1/2a proof-of-concept study evaluating the antipsoriatic efficacy of the AKVANO-calcipotriol spray formulations in patients with chronic psoriasis vulgaris was completed in July 2013. The results at day 12 showed a clear antipsoriatic effect compared with vehicle-only formulations, as confirmed by sonographic measurement and clinical assessment. The product also showed clinical efficacy comparable to that of marketed calcipotriol formulations. A phase 3 trial of the calcipotriol product is planned for 2016. An AKVANO formulation combining calcipotriol and a corticosteroid is also being developed.

The versatility of the AKVANO sprayable delivery system offers many opportunities across dermatology, wound and burn care, as well as nonpharmaceutical skin-care markets. To date, 73 active substances, including 48 active pharmaceutical ingredients, have been tested successfully in AKVANO, and various products are being developed in collaborations. For example, CCS Healthcare licensed the AKVANO technology last year and is developing skin-care products based on the new formulation. They are expected to launch in Sweden in 2016, and these will be the first examples of successful product development based on AKVANO.

More recently, a partnership between Aurena Laboratories and Lipidor was announced in June 2015, which will combine the AKVANO sprayable formulation with Aurena's bag-on-valve packaging technology for liquid products. The combination will be available to companies wishing to develop new products or improve existing ones.

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