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ICYMI: FDA Approves RhodoLED XL Lamp Red Light Source for Use in Actinic Keratosis Treatment

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Biofrontera's red light source is approved for use in combination with aminolevulinic acid hydrochloride (Ameluz) topical gel, 10%.

[Biofrontera Inc. recently announced that the US Food and Drug Administration \(FDA\) has approved its red light source](#), the [RhodoLED XL lamp](#), for treating mild to moderate actinic keratosis of the face and scalp, used in combination with aminolevulinic acid hydrochloride (Ameluz) topical gel, 10%.¹



The state-of-the-art red light emitting LED lamp is designed to revolutionize photodynamic therapy for actinic keratoses, aimed at enhancing the ease of use for health care providers by being highly maneuverable and capable of accommodating various patient treatment positions.

Image Credit: © [Calin](#) - stock.adobe.com

Biofrontera's photodynamic therapy drug, Ameluz, a photosensitizing agent and porphyrin precursor, is FDA-approved for use in combination with both RhodoLED lamp models and for lesion-directed and field-directed treatment of actinic keratoses of mild to moderate severity on the face and scalp.

IPR2025-00287

Biofrontera Inc. et al v. Sun Pharmaceutical Industries, Inc.

Sun Pharmaceutical's Exhibit 2054

EX2054, Page 1

In 2021, the [FDA approved Biofrontera's BF-RhodoLED XL lamp](#) model, a larger model building upon the successes of BF-RhodoLED, its predecessor.²



Biofrontera RhodoLED XL. Image Credit: © Biofrontera Inc.

The newly-introduced model provides clinicians with the ability to illuminate a larger treatment area in a single session, which is particularly advantageous for treating extensive or multiple lesions. Versus the existing lamp from Biofrontera, the RhodoLED XL lamp model features 5 illumination panels versus 1, and also possesses positioning sensors.

Hermann Luebbert, PhD, CEO of Biofrontera, expressed his excitement about the new product.

"We are delighted to introduce the RhodoLED XL lamp to the dermatology community in the US. This new device underscores our commitment to innovation and excellence, providing dermatologists with a powerful tool to deliver superior patient care," Luebbert said in a news release.¹ "The XL lamp's advanced features and user-friendly design will undoubtedly set a new standard in photodynamic therapy."

Luebbert also highlighted the immediate market impact, revealing that 3 RhodoLED XL devices were shipped within the first week of the launch.

"The response from dermatology organizations across the US has been very encouraging," he said.

Cleaver Dermatology, a practice with locations in Missouri and Georgia, was the first to integrate the RhodoLED XL into their operations.

David Cleaver, DO, FAOCD, the practice's lead dermatologist, shared his satisfaction with the new device.

"We are honored to be the first to integrate the XL lamp into our practice," Cleaver said. "The advanced features and versatility of this device represent a considerable upgrade on what has been available until now and will allow us to provide our patients with the highest standard of care."

For dermatologists and health care providers interested in the RhodoLED XL, Biofrontera has made it easy to request more information. Interested parties can visit [Biofrontera's contact page](#) to learn more about the product and its potential benefits for their practice.

References

1. Biofrontera announces the launch of a new, FDA-approved red light source, the RhodoLED XL lamp. News release. BioSpace. June 24, 2024. Accessed July 2, 2024. <https://www.biospace.com/article/releases/biofrontera-announces-the-launch-of-a-new-fda-approved-red-light-source-the-rhodoled-xl-lamp/>
2. Biofrontera AG receives FDA-approval of the BF-RHODOLED XL lamp. News release. Biofrontera Inc. October 22, 2021. Accessed July 2, 2024. <https://www.biofrontera.com/en/investors/financial-announcements/ad-hoc-news/pta-adhoc-biofrontera-ag-biofrontera-ag-receives-fda-approval-of-the-bf-rhodoledr-xl-lamp>

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