

Zydus receives final approval from USFDA for Ammonium Lactate Cream, 12%

Ahmedabad, India, 14 February, 2026

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as “Zydus”) has received final approval from the United States Food and Drug Administration (USFDA) for Ammonium Lactate Cream, 12% (USRLD: Lac-Hydrin Cream®, 12%).

Ammonium lactate cream, 12% is a topical prescription medication indicated for the treatment of dry, scaly skin (xerosis) and an inherited dry skin condition called ichthyosis vulgaris. It is used to moisturise the skin by increasing hydration and, as an alpha-hydroxy acid, helps relieve itching, soften skin, and decrease skin scaling.

Ammonium lactate cream will be manufactured at the group’s topical manufacturing site at Changodar, Ahmedabad, and distributed by Viona Pharmaceuticals Inc.

Ammonium lactate cream had annual sales of USD 15 mn in the United States (IQVIA MAT December 2025).

The group now has 430 approvals and has so far filed 505* ANDAs since the commencement of the filing process in FY 2003-04.

*(*As on 31-Dec-2025)*



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