

Title: Effectiveness and Tolerability of Low-Dose Micronized-Isotretinoin in Patients with Severe Recalcitrant Nodular Facial Acne in India: A Real-World Retrospective Study using Electronic Medical Records

Short title: Low-Dose Micronized-Isotretinoin in Severe Recalcitrant Nodular Facial Acne: A Real-World Study

Authors:

Byalakere S Chandrashekhar¹, Maya Vedamurthy², Seetharamanjaneyulu Kolalapudi³, Vijaya Bhaskar Mallela⁴, Shahnaz Arsiwala⁵, Anil Ganjoo⁶, Abir Saraswat⁷, Farida Modi⁸, Soumya C Sujatha⁹, Satish Udare¹⁰, Suroit Gorai¹¹, Mukesh Gabhane¹², Bhavesh Lalan¹², Gaurang Jani¹³, Aditi Jain¹³, Shruti Dharmadhikari¹³, Chintan Khandhedia¹³, Prashant Devkare¹², Amey Mane¹³, Suyog Mehta¹³

¹Cutis Academy of Cutaneous Sciences, Bangalore, India

²RSV Skin Clinic, Chennai, India

³Skin Clinic, Guntur, India

⁴OMNI Hospitals, Hyderabad, India

⁵Advanced Dermatology Solutions, Mumbai, India

⁶Skinnovation Clinics, Delhi, India

⁷Skin Clinic, Lucknow, India

⁸Modi Clinic, Mumbai, India

⁹KIMS Hospital, Bangalore, India

¹⁰Sparkle Skin and Aesthetic Centre, Mumbai, India

¹¹Apollo Multispeciality (former Gleneagles) Hospital, Kolkata, India

¹²Sun Pharmaceutical Industries Ltd., Mumbai, India

¹³Sun Pharmaceutical Industries Ltd., Mumbai, India

Corresponding author:

Dr Bhavesh Lalan,

Senior Manager, Medical Affairs, Sun Pharmaceutical Industries Ltd.

Mumbai – 400063, Maharashtra, India

Email: Bhavesh.Lalan@sunpharma.com

Supplementary tables

Table S1: Dose strength details of micronized-isotretinoin as prescribed on respective timepoint

Proportion of patients (N=305)				
Timepoint	Micronized-isotretinoin 8mg, n (%)	Micronized-isotretinoin 16mg, n (%)	Micronized-isotretinoin 24mg, n (%)	Information unavailable, n (%)
Baseline	92 (30.16%)	184 (60.33%)	29 (9.51%)	-
8±2 weeks	99 (32.46%)	174 (57.05%)	27 (8.85%)	5 (1.64%)
12±2 weeks	120 (39.34%)	156 (51.15%)	27 (8.85%)	2 (0.66%)
16±2 weeks [§]	109 (35.74%)	116 (38.03%)	28 (9.18%)	0 (0%)

[§]52/305 (17.05%) were not prescribed micronized-isotretinoin beyond 16±2 weeks

Table S2: Administration frequency details of micronized-isotretinoin as prescribed on respective timepoint

Proportion of patients						
Timepoint	Once daily, n (%)			Alternate days, n (%)	Twice a week, n (%)	Skip, n (%)
	Night	Morning	Overall			
Baseline	229 (75.08%)	76 (24.92%)	305 (100.00%)	-	-	-
8±2 weeks	225 (73.77%)	74 (24.26%)	299 (98.03%)	1 (0.33%)	-	5 (1.64%)
12±2 weeks	228 (74.75%)	74 (24.26%)	302 (99.17%)	1 (0.33%)	-	2 (0.66%)
16±2 weeks [§]	138 (45.24%)	73 (23.93%)	211 (69.18%)	35 (11.48%)	7 (2.30%)	-

[§]52/305 (17.05%) were not prescribed micronized-isotretinoin beyond 16 ± 2 weeks.

Table S3: Acne severity from baseline to end of treatment as per Investigator's Global Assessment (IGA) scale

Proportion of patients (N=305)					
	0 (Clear), n (%)	1 (Almost clear), n (%)	2 (Mild), n (%)	3 (Moderate), n (%)	4 (Severe), n (%)
Baseline	0 (0%)	0 (0%)	0 (0%)	182 (59.67%)	123 (40.33%)
8±2 weeks	6 (1.97%)	54 (17.70%)	153 (50.16%)	85 (27.87%)	7 (2.30%)
12±2 weeks	39 (12.79%)	165 (54.10%)	71 (23.28%)	29 (9.51%)	1 (0.33%)
16±2 weeks	175 (57.38%)	105 (34.43%)	18 (5.90%)	6 (1.97%)	1 (0.33%)

Abbreviation: IGA = Investigator's Global Assessment