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Original Research Article

Exploring clinical effects and usage patterns of a daily face cleanser enriched with glycolic acid, aloe vera, and vitamin-E for acne management: a post-hoc analysis

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ABSTRACT

Background: Face cleansers are recommended as adjuncts to acne therapy to counteract the acne related manifestation like acne spots and post inflammatory hyperpigmentation (PIH). This complementary study was designed to assess the clinical impact and tolerability of glycolic acid, aloe vera and vitamin-E based face cleanser for daily use in acne patients prescribed with clindamycin, tretinoin, adapalene and benzoyl peroxide for management of acne in real-world scenario.
Methods: We conducted a retrospective review at 193 centres, focusing on individuals having acne with oily and mix skin types who used face cleanser twice a day. Total 619 cases (Δ age: 28.94±7.92 years) of acne were further analysed over a 4-week study period to study improvement in post-inflammatory hyperpigmentation, acne spot reduction and enhance skin radiance and glow using subjective assessment questionnaires.
Results: The face cleanser, when used regularly with standard of care, significantly reduced acne (43.58%), acne spots (44.85%), and PIH (46.06%) with statistical significance ($p<0.01$). Patients with oily and mix skin type, 337 (54.44%) and 264 (42.65%) rated improvement on acne spots, PIH, radiance, and glow to be good to excellent, respectively. No patients experienced serious adverse events (AEs) or cleanser-related adverse event.
Conclusions: The facial cleanser demonstrated effectiveness and tolerance in treating acne patients who were prescribed with anti-bacterial and anti-inflammatory agents. In 4-week long treatment period, the facial cleanser enhanced skin radiance and also demonstrated its worth as a beneficial inclusion in everyday skincare regimens.

Keywords: Acne, Dermocosmetics, PIH, Skin radiance, Acne spots, Facial cleanser

INTRODUCTION

Acne is the most common skin disease worldwide, with an estimated prevalence and affecting 650 million adolescents.[1-4] It affects the skin's pilosebaceous unit, which includes the hair follicle, the arrector pili muscle, and the sebaceous gland.[5] Hyperactive sebaceous glands, hyperkeratosis, the bacteria *Cutibacterium acnes*, and the pH of the skin are the four primary interdependent factors.[7] Conventional pharmacological treatments for acne include topical benzoyl peroxide, systemic/topical antibiotics, systemic/topical retinoids and hormonal therapy.[6] However, adapalene and tretinoin are associated with adverse effects like photosensitivity, pruritus, skin irritation, erythema, skin dryness, and burning.[7,8] The use of topical products alone can cause increased risk of side effects. Hence, addition of dermocosmetics like face cleanser to topical anti-acne treatment reduce side effects, provide synergistic effect, improve adherence, and acne outcomes.[9]

Cleansers are soap free, non-irritating, non-allergic, pH-balanced and oil controlling products which provide additional benefits to topical treatment by removing sebum, dirt and microorganisms from face.[9] Face cleanser containing active components like glycolic acid, aloe vera and vitamin E that are beneficial for acne, acne-prone skin and aid in preventing the lesions mentioned above. Glycolic acid has anti-inflammatory, keratolytic, and antioxidant properties.[1010] It has also been effective in removing acne, acne spots, acne scars and post-inflammatory hyperpigmentation.[9-13] By revealing its antioxidant action, vitamin E is recognized to shield cellular membranes from free radicals.[14] Antioxidant vitamin E acetate protects the skin from the damaging effects of UV radiation by scavenging free radicals and minimizing possible harm. Aloe vera has anti-inflammatory, anti-irritant, moisturising, wound-healing, and antibacterial characteristics.[15-17] This study was conducted in outpatient settings across India with an objective to assess clinical impact and tolerability of a face cleanser containing glycolic acid, aloe vera, and vitamin E as an adjunct standard of care in managing patients with acne, acne spots and post-inflammatory hyperpigmentation in oily and mix skin types. The assessment of effectiveness and tolerability was based on the Investigator as well as the patients' feedback on the facial cleanser.

METHODS

Study design and patient population

This complement study was a post-approval, cross-sectional, observational, single-arm, non-comparative, multicenter, patient reported outcome based clinical study to evaluate the safety and clinical impact of a face cleanser formulated with glycolic acid, aloe vera and vitamin E for daily use in treatment of acne. Study was conducted from June 2023 to July 2023 at 193 clinical centres across India. The study included 834 participants (aged ≥18 years) who were prescribed clindamycin, tretinoin, adapalene, and benzoyl peroxide along with a face cleanser as adjuvant therapy for acne management. Out of these, 619 (70.22%) individuals with the oily and mix skin types and the acne were part of the intention-to-treat (ITT) population. Patients with allergic skin diseases other than cases of acne were excluded from the study.

Procedure

The study focused on case records of patients who completed a 4-week long therapy with twice daily (liberal) usage of face cleanser. Notably, there were no lost to follow up cases found during the study period suggesting the positive effects of face cleanser. The study utilized the patient global assessment (PGA) scale to assess treatment effectiveness. The advantage of PGA is its applicability in both clinical practice and research, allowing for a comprehensive evaluation of treatment outcomes. By incorporating patient-reported outcomes, PGA enhances the understanding of treatment efficacy. A post-hoc analysis was conducted on the oily and mix type subgroup to explore specific aspects and variables of interest.

The study consisted of two visits. At visit 1, referred to as the screening visit, all the patients were prescribed with the face cleanser and were followed up for 4 weeks ±2 days. During this visit, inclusion/exclusion criteria were evaluated, and various aspects such as demographics, physical examination (including age, height, weight, body mass index), medical and surgical history, smoking and alcohol intake, current treatment history, and assessment of concomitant medication were recorded. The outcome assessment for parameters like acne, acne spots, post-inflammatory hyperpigmentation and skin radiance, including PGA for improvement and safety evaluation, was conducted at visit 2 after a duration of 4 weeks ±2 days. A PGA was also conducted to evaluate improvement assessment at visit 2.

As the study was conducted in a real-life setting, the study medication was prescribed by the attending dermatologist, and patients obtained the drug from local pharmacy outlets. Compliance was assessed using case record sheets, and source data was reviewed to ensure compliance. Participants were considered to have completed the study if they adhered to the 4-week treatment period (with twice daily application), which was recorded in the case record form.

During the entire study duration, close monitoring and documentation of and treatment-emergent adverse events (TEAEs) was done. No AEs or TEAEs were detected or reported in any of the patients throughout the entire duration of the study.

The study was conducted in accordance with the declaration of Helsinki (Brazil, October 2013), good

clinical practices for clinical research in India 2005, new drugs and clinical trials rules 2019, ICH GCP E6 (R2) guidance on good clinical practice, and with ICMR's National ethical guidelines for biomedical and health research involving human participants, 2017. The approval from independent ethics committee was also obtained before the commencement of the study for each centre. The study was registered with the clinical trials registry of India (CTRI/2023/06/053763).

Face cleanser

The facial cleanser contains active constituents including glycolic acid, aloe vera, and vitamin E. Additionally, it comprises various other elements like purified water, acrylate copolymer, sodium laureth sulfate, polysorbate 80, sodium cocoyl, apple amino acid, decyl glucoside, colored milicapsules, phenoxyethanol, fragrance, and potassium hydroxide. Throughout study, participants applied face cleanser twice daily or as instructed by medical professional, spanning four-week timeframe (Table 1).

Table 1: Study drug.

Parameter(s)	Treatment
Product name	Ahaglow face cleanser, ingredients list: Purified water, acrylate copolymer, sodium laureth sulphate, aloe vera, polysorbate 80, sodium cocoyl, apple amino acid, decyl glucoside, coloured milicapsules, glycolic acid, phenoxyethanol, fragrance, vit E acetate, potassium hydroxide
Dosage form	Face cleanser
Dosage	Apply twice a day or as prescribe by physician
Route of administration	Topical
Manufacturer	Torrent pharmaceuticals ltd

Statistics

Patient demographic details, including both modifiable and non-modifiable risk factors, along with comorbidities, were analyzed using descriptive statistics. Frequencies and percentages were reported for qualitative variables, while means, medians, standard deviations, minimum and maximum values, and 95% confidence intervals were used to summarize quantitative variables. The significance of continuous and categorical variables was assessed using the student's paired t test, employing a two-tailed test and considering a $p<0.05$ as clinically significant. Continuous variables were presented as mean ± standard deviation, and categorical variables were represented by the number and proportion of patients. All statistical analyses were performed using SPSS software version 29.0.1.0 (171).

RESULTS

A total of 834 patients (PP population) including 619 patients (ITT population) with oily and mix skin types from 193 different locations were involved in the study and underwent one follow-up assessment to evaluate safety and effectiveness. Our analysis specifically focused on a subset of 354 female patients (57.19%) and 265 male subjects (42.81%). The delta (Δ) age, height, weight, and BMI of study participants were 28.94±7.92 years (Mean±SD), 161.05±11.13 cm (Mean±SD), 61.54±11.06 kg (Mean±SD) and 23.97±4.39 kg/m^2 (Mean±SD), respectively. Table 2 represented further details on demographic characteristics of study population. Among the entire population, 325 patients (38.97%) demonstrated high adherence, 398 patients (47.72%) displayed adequate adherence, and 111 patients (13.30%) had insufficient adherence to use of face cleanser.

Following a 4-week usage of the face cleanser, significant improvements were observed in various skin parameters when compared to the baseline (Day 00). Specifically, patients having both oily and mix skin types demonstrated statistically significant reductions ($p<0.01$) in acne by 43.58%, acne spots by 44.85%, and post-inflammatory hyperpigmentation by 46.06% (Table 4). Additionally, skin radiance displayed a remarkable increase of 84.27%, which was statistically significant with a $p<0.01$. Moreover, based on the PGA, 264 participants (42.65%) reported excellent results, 337 participants (54.44%) experienced good results, and only 18 participants (2.91%) reported fair results (Figure 2). These results suggest that the study cleanser effectively addresses diverse skin aesthetic issues and has a favorable overall influence on participants' skin health.

For individuals with oily skin, significant reductions ($p<0.01$) of 43.46% in acne, 44.33% in acne spots, and 46.54% in post-inflammatory hyperpigmentation were noted. Additionally, there was a substantial increase ($p<0.01$) of 93.67% in skin radiance (Figure 1). Likewise, those with mix skin types experienced notable reductions ($p<0.01$) of 44.18% in acne, 47.47% in acne spots, and 43.60% in post-inflammatory hyperpigmentation. They also saw a significant increase in skin radiance by 98.12% ($p<0.01$) (Figure 1).

The chi-square analysis, with an asymptotic significance value of 0.01, revealed a statistically significant connection between individuals having oily and mix skin types and the manifestation of acne. This observation underscores a substantial relationship between these variables. Consequently, it was determined that a noteworthy correlation exists between oily and mix skin types and the occurrence of acne, implying a pivotal role of these skin types in acne development. Furthermore, the study findings substantiate the fact that the usage of face cleanser yielded more favorable outcomes when utilized by patients with oily and mix skin types, as evidenced in Table 5.

Table 2: Demographic distribution of study subjects.

Variables	Per protocol population			Intent-to-treat population (Acne with oily and mix skin type)		
	Male, (n=359) (43.05%)	Female, (n=475) (56.95%)	Overall, (n=834)	Male, (n=265) (42.81%)	Female, (n=354) (57.19%)	Overall, (n=619)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age (In years)	31.28 (8.77)	27.82 (7.64)	29.31 (8.32)	30.78 (8.00)	27.56 (7.60)	28.94 (7.92)
Height (cm)	159.71 (23.94)	155.99 (18.27)	157.64 (21.01)	164.51 (12.04)	158.36 (9.56)	161.05 (11.13)
Weight (kg)	66.49 (11.01)	58.34 (10.92)	61.94 (11.70)	66.17 (11.28)	57.77 (9.33)	61.54 (11.06)
BMI (kg/m^2)	26.60 (16.97)	24.84 (29.19)	25.62 (24.55)	24.95 (5.00)	23.20 (3.67)	23.97 (4.39)

Note: n=Number of subjects, SD=Standard deviation, BMI=Body mass index.

Table 3: Count and percentage-patients characteristics.

Variables		Per protocol population		Intent-to-treat population (acne with oily and mix skin type)	
	Parameters	**Count**	**%**	**Count**	**%**
Diagnosis	Acne	718	86.09	619	100
	Acne, dryness	17	2.04	-	-
	Acne, dryness, wrinkles	1	0.12	-	-
	Acne, wrinkles	11	1.32	-	-
	Dryness	87	10.42	-	-
	Total (n)	834	100	619	100
Skin types	Oily	527	63.19	514	83.04
	Mix type	121	14.51	105	16.96
	Sensitive	19	2.28	-	-
	Dry	167	20.02	-	-
	Total (n)	834	100	619	100
Acne types	Comedones	109	13.07	77	12.4
	Cysts	59	7.07	34	5.5
	Papules	347	41.61	294	47.5
	Papules, comedones	6	0.72	3	0.5
	Papules, cysts	1	0.12	1	0.2
	Papules, pustules	21	2.52	20	3.2
	Papules, pustules, comedones	1	0.12	-	-
	Pustules	287	34.41	188	30.4
	Pustules, comedones	2	0.24	1	0.2
	Pustules, Cysts	1	0.12	1	0.2
	Total (n)	834	100	619	100
Concomitant therapy	Adapalene	274	32.85	165	26.70
	Adapalene, BPA	9	1.08	8	1.30
	Adapalene, clindamycin	231	27.70	200	32.30
	Adapalene, clindamycin, BPA	6	0.72	4	0.60
	Clindamycin, BPA, tretinoin	5	0.60	4	0.60
	Tretinoin	188	22.54	130	21
	Tretinoin, adapalene	55	6.59	48	7.80
	Tretinoin, adapalene, clindamycin	25	3	22	3.60
	Tretinoin, BPA	6	0.72	5	0.80
	Tretinoin, clindamycin	35	4.20	33	5.30
	Total (n)	834	100	619	100

Note: n=No. of subjects, "-" = Represents unavailability of data in intent-to-treat population.

Table 4: Patient assessed outcome-acne with oily and mix skin types.

Statistics	Acne				Acne spots				PIH			
	Visit 1 Baseline	Visit 2 4 weeks	CFB	%CFB	Visit 1 Baseline	Visit 2 4 weeks	CFB	%CFB	Visit 1 Baseline	Visit 2 4 weeks	CFB	%CFB
N	619	619	619	619	619	619	619	619	619	619	619	619
Minimum	0.00	0.00	-8.00	-100.00	0.00	0.00	-9.00	-100.00	0.00	0.00	-9.00	-100.00
Maximum	9.00	9.00	0.00	0.00	9.00	9.00	7.00	350.00	9.00	9.00	7.00	700.00
Mean	6.41	3.50	-2.91	-43.58	6.26	3.29	-2.97	-44.85	6.20	3.13	-3.07	-46.06
Std. error	0.07	0.07	0.08	0.97	0.08	0.07	0.08	1.22	0.08	0.06	0.08	1.54
Std. deviation	1.84	1.75	1.93	24.08	1.93	1.68	1.98	30.36	1.92	1.60	2.03	38.37
P value	<0.01				<0.01				<0.01			
95% CI	(-3.06, -2.76)				(-3.13, -2.81)				(-3.23, -2.91)			

Table 5: Patient assessed outcome-correlation between oily and mix skin type and occurrence of acne.

Variables		Value	DF	Asymptotic significance (2-sided)
Correlation between skin type and diagnosis (Acne with oily and mix skin type)	Pearson Chi-square	31.69	15	0.01
	Likelihood ratio	15.54	15	0.41
	Number of valid cases	619	-	-

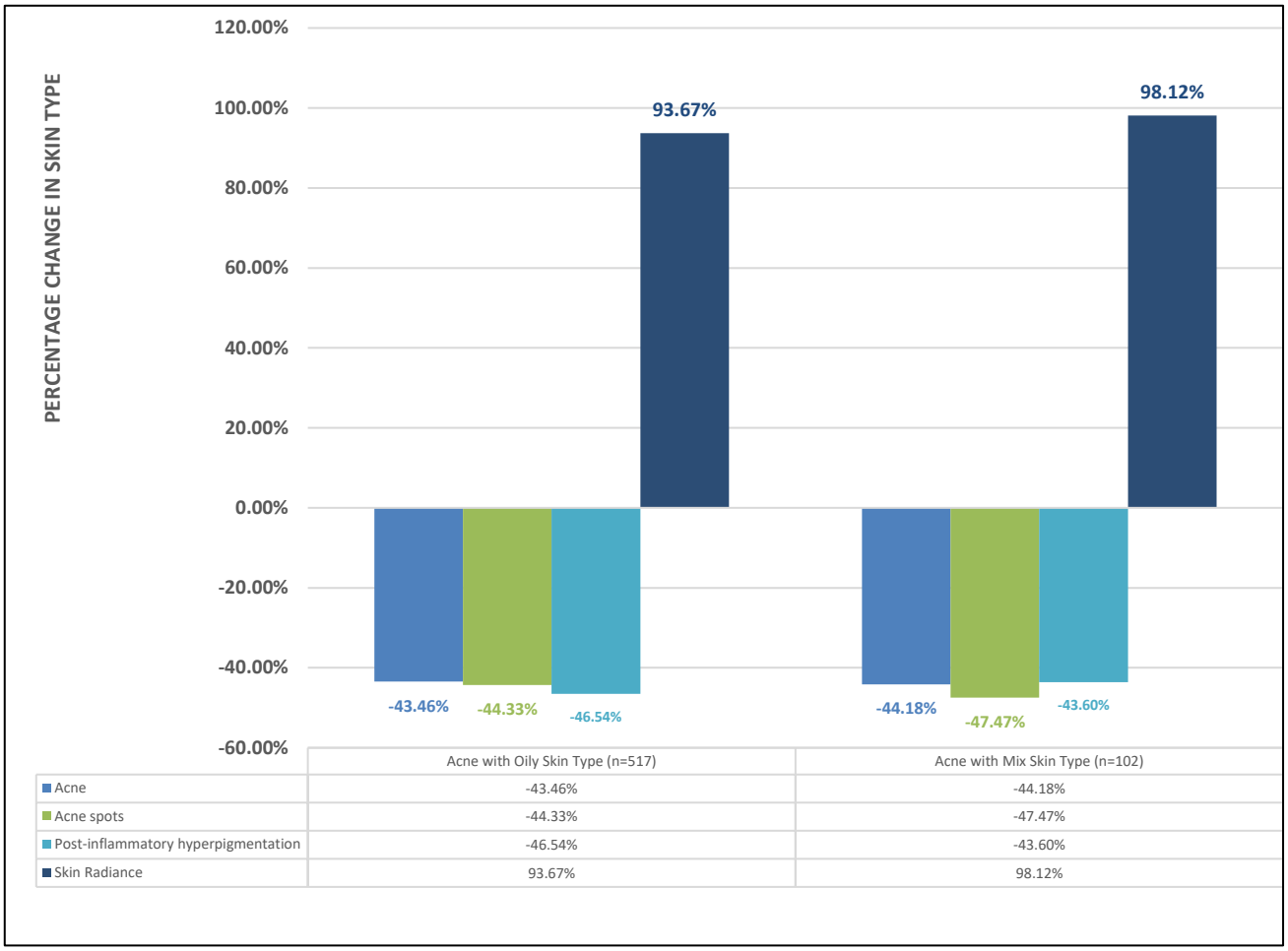

Figure 1: Effects of study product on different skin types.

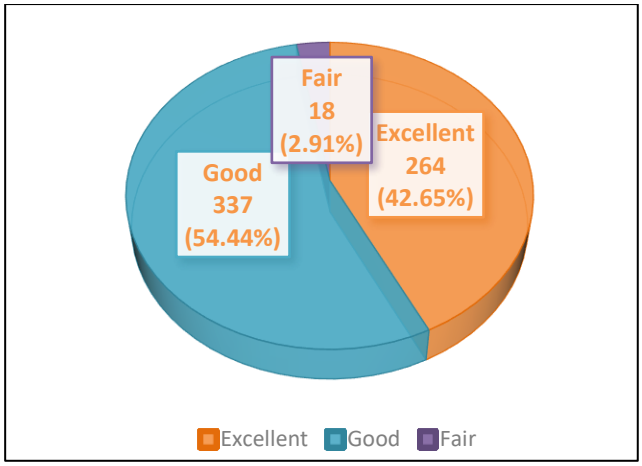

Figure 2: PGA for acne with oily and mix skin types.

DISCUSSION

The main objective of the present study was to evaluate the effects of the face cleanser on acne patients with oily and mix skin type to derived further insights on its efficacy and tolerability. A subgroup analysis was conducted on these patients to explore specific aspects and attributes of interest. This analysis was performed after the primary analysis of the study had been completed, allowing for a deeper investigation into the impact of the face cleanser on patients with acne. PGA score stated that the study produced highly favorable outcomes, aligning precisely with the predefined aim and objectives. It was proved to be highly advantageous in overcoming side effects induced by the use of anti-acne agents like tretinoin, adapalene, clindamycin and benzoyl peroxide. It may sometimes also lead to worsening of acne. Topical treatment with clindamycin (antibiotic) is used for the treatment of mild to moderate acne. Face cleansers are adjuvants used along with topical treatment. Cleansers are soap free, non-irritating, non-allergic, pH-balanced and oil controlling products which provide additional benefits to topical treatment by removing sebum, dirt and microorganisms from face. Hence, addition of dermocosmetics like face cleansers can be done to topical anti-acne treatment to reduce side effects, providing synergistic effect, improve adherence and improve acne outcome. Similarly, adjuvant therapy is also highly recommended to be added with topical tretinoin and adapalene therapy (anti-inflammatory) for improved adherence, outcome and reduced side effects due to conventional therapy. Use of aloe vera is beneficial in healing skin lesions, pus-filled lesions and reduction in acne spots.[22] In one of the studies, which involved a group of 98 patients, vitamin E stopped the bacterial-induced leaking of serum lipids through follicles and sebaceous glands, reducing inflammation and ultimately acne formation.[23] In patients with acne, glycolic acid treatment can lead to significant reductions in the number of skin lesions including acne, acne scars and post-inflammatory hyperpigmentation because of its anti-inflammatory, keratolytic, and antioxidant properties.[9-13] In this study the use of face cleanser in patients with both oily and mix skin types showed significant decrease ($p<0.01$) in acne by 43.58%, acne spots by 44.85%, and post-inflammatory hyperpigmentation by 46.06%, along with an increase ($p<0.01$) in skin radiance by 84.27%. Hence, using this face cleanser in patients with oily and mix skin type proved to be highly beneficial in terms of treatment of acne, acne spots, post-inflammatory hyperpigmentation and improved skin radiance with glow.

This clinical study's findings are in line with previous research on products containing glycolic acid, aloe vera, and vitamin E, confirming the rationality and benefits of their anti-inflammatory, keratolytic, antioxidant, antibacterial, and moisturizing effects for acne management. The investigation demonstrated that our face cleanser is tolerable, with no reported AEs. This study had some limitations that should be acknowledged. One major challenge encountered by the treating physicians was patient adherence to the study drug, which led to a loss of overall data and a reduced number of valid cases. Additionally, due to observational and non-comparative study design the findings are not supported by histological evaluation or objective/quantitative assessments. However, this study provided much needed information to dermatologists regarding the safety and efficacy of the studied formulation and demonstrated that individuals with oily and mix skin types could benefit from using the face cleanser to treat acne effectively. It proved to be successful in removing acne, acne spots, post-inflammatory hyperpigmentation, and excess oil, leaving the skin feeling fresh and exfoliated. Most noteworthy were the acceptable rating form the end users regarding improvement in skin radiance. The observation of increased skin radiance after 4 weeks of using study face cleanser suggests that the product has had a positive effect on the skin's appearance giving healthy, vibrant and glowing quality of the skin within a relatively short timeframe of 4-week therapy, indicating the effectiveness of the face cleanser in removing impurities, dirt and dead skin cells, thereby, promoting the skin's natural radiance. Therefore, our findings provide comprehensive information to the dermatologist regarding the effectiveness and tolerability of the study formulation in real world scenario.

CONCLUSION

Results of this complementary study suggest that regular use of this face cleanser reduced oiliness and a decrease in acne breakouts and reduction in acne spots and post-inflammatory hyperpigmentation. Furthermore, it enhances skin radiance, leaving the skin with a healthy glow and therefore can be used as a daily cleanser in oily and mix skin type. The face cleanser serves as an effective adjunct to pharmacotherapy for management of acne.

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