International Journal of Medical Research Professionals
P-ISSN: 2454-6356; E-ISSN: 2454-6364
DOI: 10.21276/ijmrp

IJMRP

Original Research Article.

Efficacy Evaluation of Luliconazole 1% Cream Monotherapy in Superficial Dermatophytosis: An Institutional Based Study

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ABSTRACT

Background: Superficial dermatophytosis is one of the most common fungal infections encountered in dermatology practice and continues to pose a significant therapeutic challenge because of persistent symptoms, recurrence, and variable treatment response. It commonly presents with pruritus, erythema, scaling, and annular lesions involving keratinized tissues. In recent years, there has been increasing interest in topical antifungal agents that are effective, well tolerated, and easy to use. Luliconazole 1% cream, a newer topical imidazole antifungal, has shown promising activity against dermatophytes and may be a useful option as monotherapy in localized superficial dermatophytosis.

Aim: Efficacy evaluation of luliconazole 1% cream monotherapy in superficial dermatophytosis.

Materials and Methods: This prospective, interventional clinical study was conducted in the Department of Dermatology, Gouri Devi Institute of Medical Sciences & Hospital, Durgapur, West Bengal, India. A total of 80 patients with clinically diagnosed superficial dermatophytosis were included based on predefined inclusion and exclusion criteria. After obtaining informed consent, detailed history and clinical examination were performed. Baseline assessment included demographic details, type and duration of dermatophytosis, and severity of clinical parameters such as pruritus, erythema, and scaling. All patients were treated with luliconazole 1% cream as monotherapy and were evaluated for clinical response and adverse effects. Data were entered in Microsoft Excel and analyzed using SPSS version 21.0. Continuous variables were expressed as mean ± standard deviation, categorical variables as frequency and percentage, and $p < 0.05$ was considered statistically significant.

Results: Among the 80 patients, the majority belonged to the 18–30 years age group (35.00%), and males predominated (60.00%). Tinea corporis was the most common clinical type (37.50%), followed by tinea cruris and mixed infection (25.00% each). Pruritus was present in all patients (100.00%), while erythema and scaling were observed in 90.00% and 85.00%, respectively. The mean pruritus score decreased from 2.82 ± 0.52 to 0.64 ± 0.48, erythema score from 2.60 ± 0.58 to 0.70 ± 0.49, and scaling score from 2.48 ± 0.61 to 0.68 ± 0.50 after treatment, all of which were statistically highly significant ($p < 0.001$). Complete response was seen in 65.00% of patients, partial response in 27.50%, and no response in 7.50%, giving an overall effective response rate of 92.50%. Most patients (85.00%) experienced no adverse effects, and the reported side effects were mild and localized.

Conclusion: Luliconazole 1% cream monotherapy is a safe, well-tolerated, and clinically effective treatment for superficial dermatophytosis. It significantly reduces major clinical symptoms and signs and provides a high overall therapeutic response with minimal adverse effects.

Keywords: Superficial Dermatophytosis; Luliconazole 1% Cream; Monotherapy; Clinical Efficacy; Safety.

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Article History:

Received: 26-07-2020, **Revised:** 22-08-2020, **Accepted:** 13-09-2020

Access this article online	
Website: www.ijmrp.com	Quick Response code
DOI: 10.21276/ijmrp.2020.6.5.027	

INTRODUCTION

Superficial dermatophytosis is one of the most common fungal infections encountered in dermatology practice and is caused by keratinophilic fungi that invade the stratum corneum of skin and other keratinized tissues. Clinically, it includes tinea corporis, tinea cruris, tinea faciei, tinea pedis, and related forms, which usually present with annular or polycyclic erythematous lesions, scaling, active margins, and troublesome pruritus. The condition is especially common in tropical and subtropical climates, where heat, humidity, sweating, friction, overcrowding, and close person-to-person contact promote transmission and persistence. Although often regarded as a superficial infection, dermatophytosis can cause marked discomfort, cosmetic concern, sleep disturbance,

social embarrassment, and reduced quality of life, particularly when the disease is recurrent, extensive, or inadequately treated.[1] In recent years, superficial dermatophytosis has assumed major clinical importance in India because of its changing epidemiology, increased chronicity, frequent recurrences, and therapeutic difficulty. What was once considered a relatively simple and easily manageable infection has evolved into a persistent dermatological problem in many patients. The current scenario has been linked to several interacting factors, including climatic conditions, familial spread, incomplete treatment, poor adherence, repeated self-medication, and irrational use of fixed-dose combinations containing topical corticosteroids. Such practices may modify the morphology of lesions, suppress local immune responses, mask inflammation temporarily, and contribute to atypical, widespread, or recalcitrant disease. This changing pattern has made dermatophytosis a matter of practical concern for dermatologists working in tertiary care settings.[2] Another important development in the current understanding of dermatophytosis is the recognition of changing species patterns and their possible relationship to therapeutic response. Traditional teaching emphasized *Trichophyton rubrum* as the dominant pathogen in many superficial infections, but more recent work from India has highlighted a shift in the microbiological landscape, with increasing prominence of *Trichophyton mentagrophytes* complex in chronic and difficult-to-treat disease. This evolution has renewed interest in diagnostic confirmation, clinicomycological correlation, and careful drug selection. It has also underscored the need for effective topical agents that can act rapidly, reduce fungal burden efficiently, and provide reliable symptomatic relief, particularly in localized superficial disease where topical monotherapy remains a rational first-line approach.[3] The diagnosis of superficial dermatophytosis is largely clinical, based on morphology and distribution of lesions, but laboratory support with potassium hydroxide examination and fungal culture remains valuable, especially in atypical, recurrent, or treatment-resistant cases. At the same time, management must be individualized according to extent, severity, site involved, duration, recurrence, and host factors. In limited disease, topical antifungal therapy is generally preferred because it provides direct delivery to the site of infection, minimizes systemic exposure, and is usually well tolerated. Oral antifungal therapy is typically reserved for extensive, inflammatory, chronic, recurrent, or resistant disease. Therefore, for localized superficial dermatophytosis, an effective topical agent with good skin penetration, convenient dosing, and favorable safety profile continues to hold major therapeutic relevance.[4] Among the available topical antifungal drugs, azoles remain widely used because of their broad antifungal spectrum and clinical utility. Luliconazole is a newer imidazole antifungal that has attracted attention because of its potent activity against dermatophytes and its favorable pharmacologic characteristics in the skin. It acts by inhibiting fungal ergosterol synthesis through blockade of lanosterol demethylation, thereby disrupting cell membrane integrity and fungal survival. Despite being an azole, luliconazole has demonstrated strong fungicidal activity against dermatophytes, a feature that makes it particularly attractive in cutaneous tinea. In addition, its once-daily regimen is advantageous in routine practice, where longer and more complex treatment schedules may reduce adherence and contribute to persistence or recurrence of infection.[5] The therapeutic role of luliconazole has been further strengthened by contemporary reviews emphasizing that short-course topical treatment can be clinically useful in superficial fungal infections. Agents requiring fewer applications and shorter duration are often more acceptable to patients and may improve compliance, an especially important consideration in a disease known for incomplete treatment and relapse. Luliconazole 1% cream has been used in common dermatophyte infections such as tinea corporis and tinea cruris and is regarded as a promising topical option because it combines antifungal potency with ease of application. At a time when irrational corticosteroid-containing combinations are discouraged and there is increasing emphasis on targeted antifungal therapy, luliconazole monotherapy appears to represent a rational and practical treatment strategy for uncomplicated superficial dermatophytosis.[6] Present study was conducted for efficacy evaluation of luliconazole 1% cream monotherapy in superficial dermatophytosis.

MATERIALS AND METHODS

This prospective, interventional clinical study was conducted in the Department of Dermatology, Gouri Devi Institute of Medical Sciences & Hospital, Durgapur, West Bengal, India. The study included a total of 80 patients who attended the dermatology outpatient department and fulfilled the eligibility criteria. Patients clinically diagnosed with superficial dermatophytosis were screened for inclusion in the study. Adult patients of either sex presenting with signs and symptoms suggestive of superficial fungal infection, such as erythema, scaling, pruritus, and annular lesions involving glabrous skin, were considered for recruitment. A total of 80 eligible patients who were willing to participate and provided informed consent were enrolled in the study.

Inclusion Criteria:

Patients aged 18 years and above, of either gender, with clinically diagnosed superficial dermatophytosis including tinea corporis, tinea cruris, tinea faciei, or mixed superficial dermatophytic infections, were included in the study. Patients with localized or multiple lesions who were willing to comply with treatment instructions and follow-up assessment were considered eligible.

Exclusion Criteria:

Patients with severe or extensive dermatophytosis requiring systemic antifungal therapy, pregnant or lactating women, patients with known hypersensitivity to luliconazole or any component of the formulation, and those who had received topical antifungal treatment within the recent past or systemic antifungal therapy prior to enrollment were excluded. Patients with secondary bacterial infection, chronic debilitating illness, immunocompromised status, uncontrolled diabetes mellitus, or concomitant skin disorders likely to interfere with clinical assessment were also excluded.

Methodology

Clinical Evaluation and Baseline Assessment: At baseline, a detailed history was obtained from each patient regarding age, sex, occupation, presenting complaints, duration of symptoms, site of involvement, associated itching, family history of similar lesions, personal hygiene practices, history of recurrence, and prior treatment. General physical examination and detailed dermatological examination were performed. The type, number, size, site, and extent of lesions were documented. Baseline clinical severity was assessed using relevant parameters such as

erythema, scaling, pruritus, and margin activity, and each parameter was graded using a predefined clinical scoring system. Photographic documentation of representative lesions was obtained whenever appropriate for comparative assessment.

Intervention: All enrolled patients were treated with luliconazole 1% cream as monotherapy. The cream was advised to be applied in a thin layer over the affected area and approximately 1–2 cm beyond the lesion margin after cleaning and drying the skin, as per standard dermatological practice. Patients were instructed regarding proper application technique, maintenance of personal hygiene, avoidance of sharing towels or clothes, and keeping the involved area dry and clean. No concomitant topical or systemic antifungal agents were permitted during the study period.

Outcome Measures: The primary outcome measure was clinical efficacy of luliconazole 1% cream in superficial dermatophytosis, assessed by reduction in signs and symptoms of infection. Efficacy parameters included improvement in erythema, scaling, pruritus, lesion size, lesion margin activity, and overall clinical response. The overall clinical response was categorized as complete response, partial response, or no response based on the degree of resolution of lesions and symptoms. The secondary outcome measure was safety, assessed by monitoring the occurrence of adverse drug reactions such as burning sensation, irritation, erythema, dryness, contact dermatitis, or any other local or systemic adverse effects reported by the patient or observed during clinical examination.

Assessment of Clinical Efficacy: Clinical improvement was assessed by comparing baseline findings with follow-up evaluations. Each symptom and sign, including pruritus, erythema, and scaling, was scored on an ordinal scale according to severity. The size and extent of lesions were also assessed to determine reduction in disease burden. A global assessment of therapeutic response was made by the investigator at follow-up based on the percentage improvement in clinical parameters. Complete clinical cure was defined as near total or total clearance of lesions with absence of symptoms, partial improvement as reduction in severity of signs and symptoms without complete resolution, and treatment failure as minimal or no improvement.

Safety Assessment: Safety was evaluated in all patients who received luliconazole 1% cream. Patients were specifically questioned regarding local intolerance and adverse effects during treatment. The skin at the application site was examined for erythema, irritation, dryness, burning, stinging, or worsening of lesions. All adverse events, if any, were recorded in detail with respect to onset, severity, outcome, and possible association with study medication.

Statistical Analysis: The collected data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 21.0. Descriptive statistics were used to summarize demographic and clinical variables. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequency and percentage. The change in clinical parameters before and after treatment was analyzed using appropriate statistical tests such as the paired t-test or Wilcoxon signed-rank test for quantitative or ordinal data, depending on data distribution. The association between categorical variables was analyzed using the chi-square test or Fisher's exact test wherever applicable. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1 shows the demographic distribution of the 80 patients included in the study. The largest proportion of patients belonged to the 18–30 years age group, accounting for 28 patients (35.00%), followed by the 31–40 years group with 22 patients (27.50%). Patients aged 41–50 years constituted 16 cases (20.00%), while those aged more than 50 years comprised 14 cases (17.50%). The mean age of the study population was 36.42 ± 11.28 years, indicating that superficial dermatophytosis was more commonly observed in young and middle-aged adults in this study. With regard to gender distribution, 48 patients (60.00%) were male and 32 patients (40.00%) were female, showing a male predominance.

Table 2 summarizes the clinical profile of the patients enrolled in the study. Among the various clinical types of superficial dermatophytosis, tinea corporis was the most common presentation, seen in 30 patients (37.50%). This was followed by tinea cruris and mixed infection, each observed in 20 patients (25.00%), while tinea faciei was the least common, affecting 10 patients (12.50%). With respect to disease duration, the majority of patients had symptoms for 1–3 months, comprising 34 cases (42.50%), followed by more than 3 months in 28 patients (35.00%), and less than 1 month in 18 patients (22.50%). This suggests that most patients sought medical attention only after persistence of symptoms for several weeks to months. Regarding presenting symptoms, pruritus was present in all 80 patients (100.00%), making it the most consistent complaint. Erythema was observed in 72 patients (90.00%), and scaling in 68 patients (85.00%).

Table 3 demonstrates the change in clinical severity scores following treatment with luliconazole 1% cream monotherapy. The mean pruritus score decreased markedly from 2.82 ± 0.52 at baseline to 0.64 ± 0.48 after treatment, with a mean difference of 2.18, and this reduction was found to be statistically highly significant ($p < 0.001$). Similarly, the mean erythema score declined from 2.60 ± 0.58 before treatment to 0.70 ± 0.49 after treatment, with a mean difference of 1.90, which was also statistically highly significant ($p < 0.001$). The mean scaling score decreased from 2.48 ± 0.61 at baseline to 0.68 ± 0.50 post-treatment, giving a mean difference of 1.80, again with high statistical significance ($p < 0.001$).

Table 4 presents the overall clinical response of patients to luliconazole 1% cream monotherapy. Out of the 80 patients, 52 patients (65.00%) achieved complete response, indicating near-total or total resolution of lesions and symptoms. Partial response was observed in 22 patients (27.50%), suggesting noticeable clinical improvement without complete clearance. Only 6 patients (7.50%) showed no response to treatment. When complete and partial responses are combined, the overall effective response rate was 92.50%, reflecting a high level of therapeutic efficacy of luliconazole 1% cream in superficial dermatophytosis.

Table 5 describes the safety profile and adverse effects observed during treatment. The majority of patients, 68 out of 80 (85.00%), reported no adverse effects, indicating that luliconazole 1% cream was well tolerated by most participants. Among the adverse events recorded, burning sensation was the most common, reported in 6 patients (7.50%), followed by irritation in 4 patients (5.00%), and drug-related erythema in 2 patients (2.50%). These adverse effects were mild and localized in nature. The association

between occurrence of adverse effects and treatment outcome was assessed using the chi-square test, and the p-value was 0.182, which was not statistically significant. This means that the presence of minor adverse effects did not significantly influence the final treatment response.

Table 6 evaluates whether the type of dermatophytosis had any significant influence on treatment outcome. Among patients with tinea corporis, 22 patients (73.33%) showed complete response, 6 patients (20.00%) had partial response, and 2 patients (6.67%) showed no response. In tinea cruris, 12 patients (60.00%) achieved complete response, 6 patients (30.00%) had partial response, and 2 patients (10.00%) had no response. Among those with tinea faciei, 6 patients (60.00%) showed complete response, 3 patients (30.00%) had partial response, and 1 patient (10.00%) had no response. In patients with mixed infection, 12 patients (60.00%) had complete response, 7 patients (35.00%) had partial response, and 1 patient (5.00%) showed no response. Although complete response was numerically highest in patients with tinea corporis, difference in response patterns among various clinical types was found to be statistically insignificant (p = 0.412).

Table 1: Demographic Characteristics of Study Population (n = 80)

Variable	Frequency (n)	Percentage (%)
Age Group (years)		
18–30	28	35.00%
31–40	22	27.50%
41–50	16	20.00%
>50	14	17.50%
Mean age ± SD	36.42 ± 11.28 years	
Gender		
Male	48	60.00%
Female	32	40.00%

Table 2: Clinical Profile of Patients (n = 80)

Variable	Frequency (n)	Percentage (%)
Type of Dermatophytosis		
Tinea corporis	30	37.50%
Tinea cruris	20	25.00%
Tinea faciei	10	12.50%
Mixed infection	20	25.00%
Duration of Disease		
<1 month	18	22.50%
1–3 months	34	42.50%
>3 months	28	35.00%
Symptoms		
Pruritus	80	100.00%
Erythema	72	90.00%
Scaling	68	85.00%

Table 3: Comparison of Clinical Severity Scores Before and After Treatment (n = 80)

Parameter	Baseline Mean ± SD	Post-treatment Mean ± SD	Mean Difference	p-value
Pruritus Score	2.82 ± 0.52	0.64 ± 0.48	2.18	<0.001*
Erythema Score	2.60 ± 0.58	0.70 ± 0.49	1.90	<0.001*
Scaling Score	2.48 ± 0.61	0.68 ± 0.50	1.80	<0.001*

Table 4: Overall Clinical Response to Treatment (n = 80)

Clinical Response	Frequency (n)	Percentage (%)
Complete response	52	65.00%
Partial response	22	27.50%
No response	6	7.50%

Table 5: Safety and Adverse Effects (n = 80)

Adverse Effect	Frequency (n)	Percentage (%)
Burning sensation	6	7.50%
Irritation	4	5.00%
Erythema (drug-related)	2	2.50%
No adverse effects	68	85.00%

Association between adverse effects and treatment outcome: Chi-square test: **p = 0.182** (not statistically significant)

Table 6: Association Between Type of Dermatophytosis and Clinical Response

Type of Infection	Complete n (%)	Partial n (%)	No Response n (%)	p-value
Tinea corporis	22 (73.33%)	6 (20.00%)	2 (6.67%)	
Tinea cruris	12 (60.00%)	6 (30.00%)	2 (10.00%)	
Tinea faciei	6 (60.00%)	3 (30.00%)	1 (10.00%)	
Mixed infection	12 (60.00%)	7 (35.00%)	1 (5.00%)	**0.412**

DISCUSSION

In the present study, the largest proportion of patients belonged to the 18–30 year age group (35.00%), followed by 31–40 years (27.50%), with a mean age of 36.42 ± 11.28 years, and there was a clear male predominance (60.00% males vs 40.00% females). This pattern suggests that superficial dermatophytosis was more common in young and middle-aged adults, especially men, probably because of greater sweating, friction, and occupational exposure. These findings are comparable with the study by Rajagopalan et al. (2018), who reported that the maximum number of patients belonged to the third decade of life and that there was a male preponderance among 311 cases of dermatophytosis. Thus, the demographic pattern observed in the present study is in agreement with contemporary Indian data showing that dermatophytosis predominantly affects economically active age groups and is more frequent in males.[7]

A similar demographic trend was also reported by Poluri et al. (2015) in a South Indian clinicomycological study of 110 patients, where 64.54% of cases occurred in the 21–40 year age group and 67.27% were males. In the present study, the combined proportion of patients between 18 and 40 years was 62.50% (50/80), which closely parallels their age distribution. Likewise, our male proportion of 60.00% is slightly lower than the 67.27% reported by Poluri et al., but still supports the same broad epidemiological pattern. This consistency across studies reinforces the view that young adult males remain the most commonly affected group in superficial dermatophytosis in tropical settings.[8]

With regard to the clinical profile, tinea corporis was the most common presentation in the present study, seen in 37.50% of patients, while tinea cruris and mixed infection each accounted for 25.00%, and tinea faciei for 12.50%. In addition, 42.50% of patients had disease duration of 1–3 months and 35.00% had symptoms for more than 3 months, indicating a substantial burden of persistent disease. These findings are comparable with Vineetha et al. (2019), who found that tinea corporis was the most common presentation in both first-episode and chronic dermatophytosis, and that chronic dermatophytosis was present in 68% of patients. Their observation of persistent disease and predominance of tinea corporis is in line with the present study, although our proportion with symptoms lasting more than 3 months (35.00%) was lower than the chronicity burden described in the Kerala study.[9]

The symptom profile in the present study showed that pruritus was present in 100.00% of patients, while erythema and scaling were observed in 90.00% and 85.00%, respectively. This indicates that itching was the dominant symptom and a major reason for seeking treatment. This observation is supported by Patro et al. (2019), who emphasized that pruritus is the major concern in patients with superficial dermatophytosis and that severe or prolonged itching markedly impairs quality of life. Therefore, the universal presence of pruritus in our study is clinically important, because it highlights not only disease activity but also the symptomatic burden that should improve with effective therapy.[10]

The present study demonstrated a marked reduction in symptom severity after treatment with luliconazole 1% cream. The mean pruritus score decreased from 2.82 ± 0.52 to 0.64 ± 0.48, the mean erythema score from 2.60 ± 0.58 to 0.70 ± 0.49, and the mean scaling score from 2.48 ± 0.61 to 0.68 ± 0.50, with all changes being statistically highly significant ($p < 0.001$). These findings are comparable with Jerajani et al. (2013), who, in a pilot study of dermatophytoses, found that the luliconazole group showed 70.00% resolution of pruritus, 85.00% absence of erythema, and 95.00% absence of desquamation at the end of treatment, with a 92.9% reduction in composite score. Although that study compared luliconazole with other topical agents, both studies demonstrate that luliconazole provides substantial improvement in inflammatory signs and symptoms of dermatophytosis.[11]

In the present study, 65.00% of patients achieved complete response, 27.50% showed partial response, and only 7.50% had no response, giving an overall effective response rate of 92.50%. This favorable outcome is consistent with the efficacy profile reported by Jones et al. (2014) in a multicenter randomized trial of tinea cruris, where complete clearance was achieved in 21.2% of patients treated with luliconazole compared with 4.4% in the vehicle group ($P < 0.001$). Although our complete response rate was higher than that trial, differences in disease spectrum, study design, and outcome definitions may explain the variation. Nevertheless, both studies strongly support the clinical effectiveness of luliconazole monotherapy in superficial dermatophytosis.[12]

The safety profile observed in the present study was also encouraging. Eighty-five percent of patients experienced no adverse effects, while the reported reactions were mild and localized, namely burning sensation in 7.50%, irritation in 5.00%, and drug-related erythema in 2.50%. Moreover, the association between adverse effects and treatment outcome was not statistically significant ($p = 0.182$), indicating that minor intolerance did not alter clinical efficacy. This is comparable with Jarratt et al. (2014), who reported that luliconazole had a safety profile similar to vehicle in patients with interdigital tinea pedis, while also producing significantly better efficacy, with 26.4% complete clearance in the luliconazole arm versus 1.9% with vehicle. Thus, both studies confirm that luliconazole is generally well tolerated and clinically useful.[13]

When treatment response was analyzed according to clinical subtype in the present study, complete response was highest in tinea corporis (73.33%), whereas tinea cruris, tinea faciei, and mixed infection each showed complete response rates of around 60.00%; however, this difference was not statistically significant ($p = 0.412$). This suggests that luliconazole was broadly effective across different clinical forms of superficial dermatophytosis. A similar impression of consistent efficacy across lesion types can

be inferred from the trial by Watanabe et al. (2006), in which luliconazole 1% achieved 91.5% improvement of skin lesions and 76.1% mycological negativity, outcomes that were comparable to bifonazole despite a shorter regimen. Although their study was in tinea pedis, the comparable lesion improvement supports the concept that luliconazole has stable antifungal efficacy across superficial dermatophyte infections rather than being restricted to one site alone.[14]

Overall, the present study indicates that luliconazole 1% cream monotherapy is both effective and safe in superficial dermatophytosis, with significant symptom reduction, 92.50% overall clinical improvement, and only mild adverse events. This overall impression is further supported by Watanabe et al. (2007), who in a dose-finding randomized trial reported 90.5% improvement of skin lesions and 79.7% mycological cure at week 4 with 1% luliconazole, while treatment-related adverse events were noted in only 2.6% of cases and were mild. Although their trial involved tinea pedis and our study focused on superficial dermatophytosis at other sites, both studies point in the same direction: luliconazole 1% offers strong clinical efficacy with excellent tolerability, making it a reliable topical monotherapy option.[15]

CONCLUSION

Luliconazole 1% cream monotherapy is a safe and clinically effective treatment for superficial dermatophytosis. It produced significant improvement in pruritus, erythema, and scaling, with a high overall clinical response rate. The drug was well tolerated, and most adverse effects were mild, localized, and infrequent. Thus, luliconazole 1% cream can be considered a useful topical monotherapy option for the management of superficial dermatophytosis in routine clinical practice.

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Source of Support: Nil. **Conflict of Interest:** None Declared.

Cite this article as: Himanshu Gupta, Shikha Gupta. Efficacy Evaluation of Luliconazole 1% Cream Monotherapy in Superficial Dermatophytosis: An Institutional Based Study. Int J Med Res Prof. 2020 Sept; 6(5): 116-21. DOI:10.21276/ijmrp.2020.6.5.027