Original Article

Comparative Study of The Efficacy and Safety of Topical Antifungal Agents Clotrimazole, Luliconazole, Sertaconazole in The Treatment of Tinea Corporis / Cruris: A Randomized, Comparative, Parallel Group, Open-Label Study

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ABSTRACT

Introduction: Dermatophytosis is the most common type of superficial fungal infection affecting the Indian population and the most commonly occurring clinical type of dermatophytosis include tinea corporis (36-59%) and tinea cruris (12-27%). No clinical trials were comparing Clotrimazole, Luliconazole, and Sertaconazole in the treatment of tinea corporis/cruris. Hence, this study was undertaken to compare the three antifungal drugs.

Aims and objective: To compare the efficacy and safety of Clotrimazole, Luliconazole, and Sertaconazole by comparing the mean change in the composite severity score of the target lesion from baseline to 4 weeks with respect to pruritus, erythema, vesicles, desquamation in patients with tinea corporis/cruris

Methods: It was a randomized, open-label, parallel arm, comparative study done on 75 patients of tinea visiting skin OPD of a tertiary care hospital. Patients were randomly allocated in the three treatment groups, Clotrimazole 1%, Sertaconazole 2%, and Luliconazole 1% group, and efficacy and safety were assessed at 1, 2, 3, and 4-week follow-up visits.

Results: Mean Change in composite severity score(primary endpoint) at 4 weeks was found to be significantly more in the Sertaconazole group as compared to the Luliconazole group and Clotrimazole group. Only one patient in each group developed adverse events, all of them were mild in severity and none of the patients needed treatment discontinuation.

Conclusion: Sertaconazole was more efficacious as compared to Luliconazole and Clotrimazole in patients of tinea.

Keywords: Composite score, Pruritus, Erythema, Tinea Corporis, Sertaconazole, Luliconazole, Clotrimazole.

INTRODUCTION

Dermatophytosis is the most common type of superficial fungal infection that affects as many as 20-25% of the world's population.[1] It is a significant health issue, particularly in tropical nations like India because of the hot and humid weather.[2] Dermatophytosis is classified into three generations Epidermophyton, Trichophyton, and Microsporum.[3] Tinea corporis and tinea cruris refer to the dermatophytic infections of the glabrous skin of the body (excluding palms and soles) and groins respectively.[4] Tinea corporis (36–59%) and tinea cruris (12–27%) are the two clinical types of dermatophytosis that are most frequently seen in India.[5] Dermatophytosis does not prove fatal, but it does interfere with everyday life, lead to a poor quality of life, and increase medical costs.[6] The advantages of topical therapy over oral therapy, however, include fewer side effects, the avoidance of drug-drug interactions, better compliance, and lower costs.[7,8,9]

For more than 25 years, Clotrimazole has been successfully used topically to treat tinea corporis/cruris. However, it has drawbacks such as a prolonged course of treatment that results in poor compliance and a high recurrence rate due to the early emergence of resistance.[10,11,12] The introduction of newer broad-spectrum antifungals like Luliconazole and Sertaconazole has created new treatment options to address the increasing pathogenicity of superficial fungal infections.

Luliconazole and Sertaconazole are azoles antifungals.[13] Sertaconazole exerts fungistatic and fungicidal effects that result in the fast leaking of vital intracellular components and immediate cell death.[14,15] It also has additional anti-inflammatory actions that help to provide better symptomatic relief.[16,17] These additional properties of Sertaconazole are likely to make an impact on the concomitant symptom control and therefore improve the quality of life of these patients with dermatophytosis.[18,19]

We came across no clinical studies comparing the efficacy and safety of topical antifungals Clotrimazole, Luliconazole, and Sertaconazole in the treatment of tinea corporis/cruris. Hence, this study was undertaken to compare three antifungals, conventional Clotrimazole and newer Luliconazole and Sertaconazole for the treatment of tinea corporis/ cruris.

MATERIALS AND METHODS

1. Study design

It was a randomized, prospective, open-labeled, parallel-group, comparative study carried out in a tertiary care hospital in central India from January 2021 to August 2022. A total of 75 patients visiting skin OPD suffering from tinea corporis/ cruris as diagnosed by a dermatologist were included in the study.

The study was carried out after approval from the institutional ethics committee and carried in accordance with Good Clinical Practice (GCP) guidelines and the ethical principles as mentioned in the declaration of Helsinki and ICMR guidelines. A written informed consent was taken from each subject after explaining to them the nature of the study and a copy of the patient information sheet was given.

2. Subject eligibility

Inclusion criteria

1. Patients with clinical manifestations of cutaneous mycoses (tinea corporis/ cruris).

2. Patients of 18-65 years of age.

3. Patients of either gender.

4. Patient willing to give written informed consent.

5. Combined pruritus, erythema, vesicles, and desquamation score of at least 5.

Exclusion criteria

1. Patients with a history of hypersensitivity to azole drugs or vehicle ingredients.

2. Patients with pregnancy and lactating mothers.

3. Patients with a known history of severe cardiac, pulmonary, gastrointestinal, renal, hepatic, neurological disease and uncontrolled diabetes mellitus.

4. Patients with previous treatment with antifungal, antibiotic, or immunosuppressant agents.

5. Patients with other dermatological conditions.

6. Patients with treatment-resistant cases (requiring systemic drug intervention).

Demographic data and relevant medical history were noted. Patients were assessed for the efficacy and safety of the drug. Patients were eligible for the study if they had a combined score of at least 5. The eligible patients were randomly allocated into the following three treatment groups using a computer-generated table of random numbers –

Group A - Topical Clotrimazole 1% cream

Group B - Topical Sertaconazole 2% cream

Group C - Topical Luliconazole 1% cream

The test medication in each group was advised to be applied 12 hourly on the affected lesion. The patients in all three groups were advised to apply the cream over the affected area and 1 inch surrounding that area in a thin layer. Drugs were procured by the principal investigator and distributed to the patients free of cost. There was no financial burden on the patients. The total duration of the treatment was 4 weeks.

Patient demographic data including age, sex, and baseline clinical parameters such as pruritus, erythema, vesicles, and desquamation were noted at the first visit. All patients were followed up on the 1st week, 2nd week, 3rd week, and 4th week for efficacy and safety. Outcome of the treatment was assessed by the clinical care as per the 4 Point Physician Global Assessment scale. An empty study medication tube distributed to patients on previous follow-up visits was collected from them at subsequent follow-up visits to check for adherence and thereafter new sealed tube of study medication was given for 1 week to the individual patient.

4. Efficacy and safety assessment

The primary efficacy parameter was the change in the composite signs and symptoms severity score of the target lesion using 4-Point Physician Global Assessment Scale at the end of 4 weeks.[14,20,21] The signs and symptoms that will be evaluated are pruritus, erythema, vesicles, and desquamation. These signs and symptoms will be graded as absent (0), mild (1), moderate (2), and severe (3). The safety of the study medication will be assessed in all patients by recording adverse drug events as reported by them.

6. Statistics

Sample size

A difference of 1 unit in composite signs and symptoms severity score of the target lesion between the groups from baseline to 4 weeks assuming a standard deviation of 1.12 with 0.05 level of significance and power 80% was taken from previous studies.[22] After putting all these values in PS software version 3.1.6 the calculated sample size came out to be 25 in each group. Taking into consideration 20% dropout, the final sample size in each group was taken as 21.

Statistical analysis

Patients were included for analysis on a per-protocol basis. Descriptive statistics were reported as percentages. Continuous parametric variables were expressed as mean ± standard deviation (SD). Categorical variables were expressed in actual numbers and percentages. Within-group comparison of the mean severity score at each follow-up visit was done by repeated measures ANOVA. Differences in clinical scores between groups were compared by one-way analysis of variance (ANOVA). A difference was considered significant if the $P<0.05$. Post hoc test were applied to find out between which two

groups the difference exists. Statistical analysis was performed using graph pad prism version 8.4.2.

RESULTS AND DISCUSSION

A total of 110 patients were screened, out of which 35 did not meet the eligibility criteria; hence were not included in the study. A total of 75 patients were randomized and allocated to three treatment groups. Patients who did not return for follow-up visits were termed as loss to follow-up. Per protocol analysis was followed and all the patients who did not show up for follow up were excluded from the analysis.

Demographic details

All 75 patients were analyzed for demographic parameters. Table 1 shows the demographic characteristics of patients at baseline, occupation, and education details and also shows a comparison of demographic characteristics of patients in group A, group B, and group C. The mean age and gender distribution of patients in the Clotrimazole group, Sertaconazole group, and Luliconazole group were not significantly different from each other and groups A, group B, and group C were comparable at baseline.

Table 1: Demographic characteristics (n = 75)

	37.09±13.31			
	Group A (n=24)	**Group B (n=22)**	**Group C (n=23)**	**P value**
Age (years)	34.54±12.69	39.27±14.56	38.3±12.79	0.4767
	1	1	1.3	0.8285
Female: Male	1.02			
Occupation	**No of participants**			
Housewife	22 (29.33%)			
Farmer	2 (2.66%)			
Govt service	3 (4%)			
Private service	20 (26.66%)			
Labour	5 (6.66%)			
Other	23 (30.66%)			
Education				
Up to SSC	11 (14.66%)			
Up to HSC	15 (20%)			
Undergraduate	4 (5.33%)			
Graduate	45 (60%)			

values are expressed as mean ± sd (standard deviation); group a – topical Clotrimazole 1% cream; group b – topical Sertaconazole 2% cream; group c – topical Luliconazole 1% cream

Table 2: Comparison of baseline score between three treatment groups

Parameter	Group A (n=24)	Group B (n=22)	Group C (n=23)	P value
Pruritus	2.54±0.78	2.63±0.58	2.65±0.71	0.8474
Erythema	2.79±0.41	2.59±0.73	2.65±0.48	0.4526
Vesicle	2.20±0.88	2.40±0.80	2±1.04	0.3459
Desquamation	2.41±0.77	2.40±0.59	2.2±0.69	0.5104
Composite score	9.95±1.63	10.04±1.29	9.5±1.65	0.4499

values are expressed as mean ± sd (standard deviation), p-value < 0.05 was considered significant; group a – topical Clotrimazole 1% cream group b – topical Sertaconazole 2% cream; group c – topical Luliconazole 1% cream

When comparing baseline scores of patients according to parameters (Pruritus, Erythema, Vesicle, Desquamation, and Composite score) in group A, group B, and group C, it was observed that there was no significant difference between the groups. (Table 2)

Table 3: Within-group comparison of mean score of Pruritus, Erythema, Vesicle, Desquamation, and Composite score at baseline, 1st week, 2nd week, 3rd week, and 4th week in all the three treatment groups

Groups	Parameters	Baseline	1st week	2nd week	3rd week	4th week	P value
Group A	Pruritus	2.54 ± 0.78	1.91± 0.77*	1.20 ± 0.72*#	0.58 ± 0.58*#$	0.20 ± 0.41*#$^	<0.0001
	Erythema	2.79 ± 0.41	2.6 ± 0.49	1.91 ± 0.50*#	1.37 ± 0.49*#$	0.87 ± 0.45*#$^	<0.0001
	Vesicle	2.20 ± 0.88	1.87 ± 0.85*	1.33 ± 0.70*#	1.00 ± 0.66*#	0.54 ± 0.51*#$^	<0.0001
	Desquamation	2.41 ± 0.77	2.04 ± 0.81*	1.33 ± 0.70*#	0.87 ± 0.61*#$	0.41 ± 0.50*#$^	<0.0001
	Composite severity score	9.95 ± 1.63	8.45 ± 1.53*	5.79 ± 1.50*#	3.83 ± 1.43*#$	2.04 ± 0.95*#$^	<0.0001
Group B	Pruritus	2.63 ± 0.58	1.09 ± 0.75*	0.40 ± 0.50*#	0.09± 0.29*#$	0*#$	<0.0001
	Erythema	2.59 ± 0.73	1.90 ± 0.43*	1.22 ± 0.53*#	0.95 ± 0.21*#	0*#$^	<0.0001
	Vesicle	2.40 ± 0.80	1.54 ± 0.67*	0.77 ± 0.43*#	0.13 ± 0.35*#$	0*#$	<0.0001
	Desquamation	2.40 ± 0.59	1.36 ± 0.58*	0.72 ± 0.45*#	0.18 ± 0.39*#$	0*#$	<0.0001
	Composite severity score	10.04 ± 1.29	5.90 ± 1.41*	3.13 ± 1.04*#	1.36 ± 0.85*#$	0*#$^	<0.0001
Group C	Pruritus	2.65 ± 0.71	1.69 ± 0.63*	1.04 ± 0.47*#	0.39 ± 0.50*#$	0*#$^	<0.0001
	Erythema	2.65 ± 0.48	2.21 ± 0.51*	1.65 ± 0.49*#	1.08 ± 0.42*#$	0.47 ± 0.51*#$^	<0.0001
	Vesicle	2.00 ± 1.04	1.56 ± 0.84*	1.08 ± 0.60*#	0.65 ± 0.49*#$	0.04 ± 0.21*#$^	<0.0001
	Desquamation	2.26 ± 0.69	1.60 ± 0.72*	1.13 ± 0.46*#	0.52 ± 0.51*#$	0.13 ± 0.34*#$^	<0.0001
	Composite severity score	9.56 ± 1.65	7.08 ± 1.70*	4.91 ± 1.31*#	2.65 ± 1.30*#$	0.65 ± 0.65*#$^	<0.0001

values are expressed as mean ± sd (standard deviation); repeated measures annova test with tukey's multiple comparison post hoc test, *p-value <0.05 as compared to baseline, # p value <0.05 as compared to 1 week, $ p value <0.05 as compared to 2 weeks, ^p value <0.05 as compared to 3 week.
group a – topical Clotrimazole 1% cream; group b – topical Sertaconazole 2% cream; group c – topical Luliconazole 1% cream

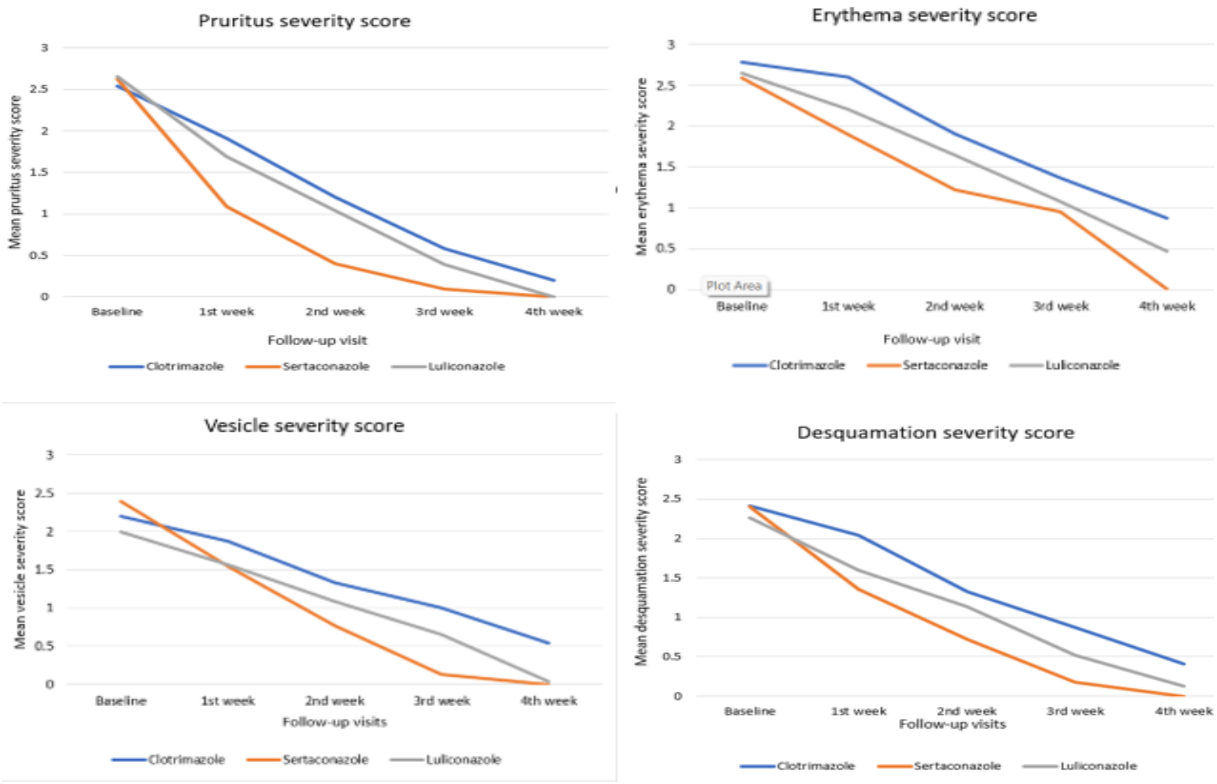

Figure 1: Mean severity score of all 4 parameters in each follow up visits

Table 4: Comparison of mean change in composite severity score from baseline at 1st, 2nd, 3rd, and 4th week between three treatment groups

Parameter	Duration	Group A	Group B	Group C	P value
Composite score	Baseline to 1st week	1.5±1.02	4.13±1.17*#	2.47±0.99*	<0.0001
	Baseline to 2nd week	4.16±1.27	6.90±1.30*#	4.65±1.46	<0.0001
	Baseline to 3rd week	6.12±1.39	8.68±1.36*#	6.91±1.16	<0.0001
	Baseline to 4th week	7.91±1.32	10.04±1.29*#	8.91±1.62*	<0.0001

values are expressed as mean ± sd (standard deviation); one-way anova followed by post hoc tukey's test, * p-value < 0.05 compared to Clotrimazole, # p value ≤ 0.05 compared to Luliconazole.

group a – topical Clotrimazole 1% cream; group b – topical Sertaconazole 2% cream; group c – topical Luliconazole 1% cream

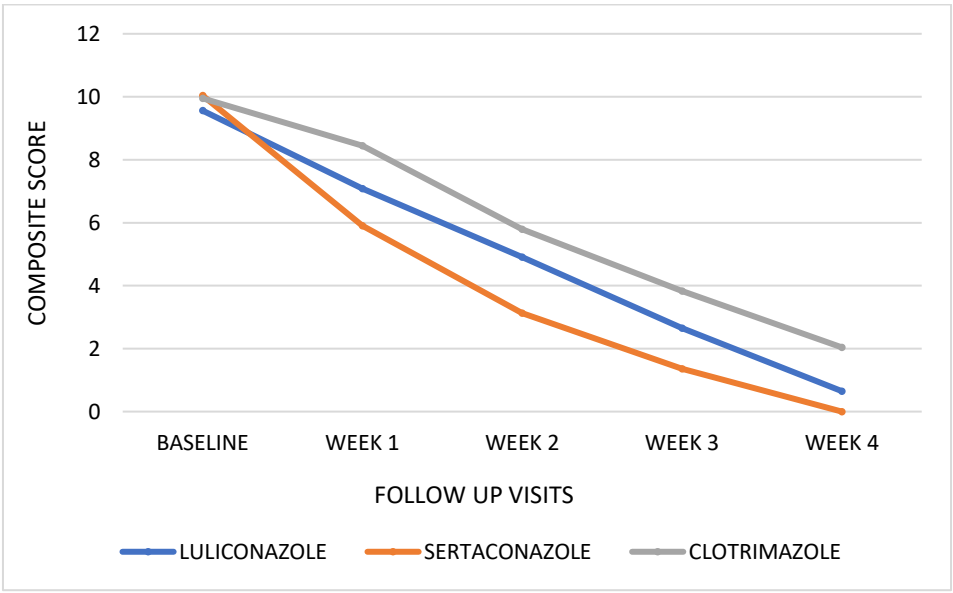

Figure 2: Comparison of composite severity score between the 3 groups from baseline to week 4

A comparison of pruritus, erythema, vesicle, desquamation, and composite score within the group at 1st week, 2nd week, 3rd week, and 4th week of treatment was done which revealed significant differences in mean pruritus, erythema, vesicle, desquamation, and composite severity score between follow up visits in all the three groups. (Table 3) and Figure 1 shows a trend in the decline of the mean severity score of all 4 parameters at each follow-up visit in the three-treatment group.

When a comparison of mean change in composite severity score at 1st, 2nd, 3rd, and 4th week between three treatment groups was done, a significant difference in composite severity score was seen between Clotrimazole, Sertaconazole, Luliconazole group (p-value < 0.0001). The exact significant difference in mean change in composite severity score between Luliconazole vs Sertaconazole (p value< 0.0001), Luliconazole vs Clotrimazole (p-value = 0.0067), and Sertaconazole vs Clotrimazole (p-value < 0.0001) at 1st week. In 2nd week significant difference in mean change in composite severity score between Luliconazole vs Sertaconazole (p-value < 0.0001) and Sertaconazole vs Clotrimazole (p value < 0.0001) was seen. However, there was no significant difference between Luliconazole vs Clotrimazole (p value = 0.4387). A significant difference in mean change in composite severity score between Luliconazole vs Sertaconazole (p-value < 0.0001) and Sertaconazole vs Clotrimazole (p-value < 0.0001) was seen in 3rd week. However, there was no significant difference between Luliconazole vs Clotrimazole (p value = 0.1058). In 4th week exact significant difference in mean change in composite severity score between Luliconazole vs Sertaconazole (p-value = 0.0249), Luliconazole vs Clotrimazole (p-value = 0.0487), and Sertaconazole vs Clotrimazole (p-value < 0.0001) was observed, (Table 4)

In Figure 2, there was a decline in the trend of composite severity score from baseline to 4 weeks in the Clotrimazole, Sertaconazole, and Luliconazole groups, indicating a consistent decrease in composite severity score in all three groups, more so in the Sertaconazole group.

All three drugs i.e., topical Clotrimazole, topical Sertaconazole, and topical Luliconazole were well tolerated and safe. Adverse events reported were mild and did not need discontinuation of the drug. However, one patient in each group presented with mild adverse events. Not a single patient discontinued the treatment because of adverse events.

DISCUSSION

A total of 75 patients of both genders were included in the study, with 25 patients in each group. A statistically significant difference was not seen in baseline demographic data and clinical characteristics of participants of the study. In this study, the majority of the patients belonged to the middle age group (mean age 37 years) with a female-male ratio of 1.02.

Our study assessed the P value for mean change in composite score which was significant at the end of 4 weeks for Sertaconazole as compared to Clotrimazole and Luliconazole and Luliconazole as compared to Clotrimazole.

There was a significant reduction in clinical features (pruritus, erythema, vesicles, and desquamation) as compared to the baseline in all three study groups.[22,23,24] As of all 4 clinical parameters, pruritus was considered an important clinical parameter that brought the patient to OPD, and it was the parameter that needed to be resolved early. Our study found that Sertaconazole shows a faster reduction (as early as 1st week) in the mean score of pruritus compared to Luliconazole and Clotrimazole from baseline. This early reduction shown by Sertaconazole is probably because Sertaconazole has additional anti-inflammatory and antipruritic action.[17] This finding was similar to the study done by Satish et al.[22] Khan et al.[5]

Our study found that Sertaconazole showed a significant reduction in the mean score of erythema, vesicle, and desquamation at the end of 1st week compared to Luliconazole and Clotrimazole from baseline. This finding is similar to the study done by Satish et al which compared Clotrimazole vs Sertaconazole and found that Sertaconazole shows a faster reduction in the mean score of erythema, vesicle, and desquamation.[22] A study done by Kaur et al compared Luliconazole vs Clotrimazole and found that Luliconazole showed a reduction in the mean score of erythema, vesicle, and desquamation at the end of 2nd week.[20] However, Dakhale et al compared Luliconazole vs Sertaconazole showed a significant difference in mean erythema, vesicle, and desquamation score at the end of 4th week and found that Sertaconazole is better as compared to Luliconazole.[24]

The adverse events in our study, all three creams were well tolerated and safe. Adverse events reported were mild and did not report the discontinuation of the drug. One (out of twenty-four) patients in the Clotrimazole group presented with dry skin and rash. This finding was similar to the study done by Lakshmi Prabha M et al.[21] One (out of twenty-two) patient in the Sertaconazole group showed a burning sensation at the site of application, which was of mild grade and experienced by patients for just 2–3 days. It did not require any stoppage of medication, shift to another therapy, or withdrawal of the patient from the trial. A similar result was shown by Dakhale et al.[24] One (out of twenty-three) patient in the Luliconazole group showed irritation and peeling of the skin, this finding was similar to the study done by Chandana et al.[1]

Limitations of the study: This is an open-label study hence probability for bias cannot be excluded.

CONCLUSION

All three topical drugs i.e., Clotrimazole 1%, Sertaconazole 2%, and Luliconazole 1% were found efficacious in tinea corporis/cruris but Sertaconazole 2% was found to be superior in efficacy as far as physician global assessment scale for composite severity score. All three drugs were safe and well tolerated and can be used in patients with tinea corporis/ cruris.

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