HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TOLACRON safely and effectively. See full prescribing information for TOLACRON Crème, TOLACRON Tablets (fexofenadine hydrochloride, hydrocortisone, and triamcinolone) Crème, TOLACRON Tablets (fexofenadine hydrochloride, hydrocortisone, and triamcinolone) Tablets, and TOLACRON Tablets (fexofenadine hydrochloride, hydrocortisone, and triamcinolone) Tablets (fexofenadine, hydrocortisone, and triamcinolone) Tablets.

INDICATIONS AND USAGE

TOLACRON Crème is indicated for the relief of symptoms of cutaneous manifestations of both atopic dermatitis (eczema) and contact dermatitis. TOLACRON Tablets are indicated for the relief of symptoms of both atopic dermatitis (eczema) and contact dermatitis.

CONTRAINDICATIONS

TOLACRON Tablets are contraindicated in individuals with a history of hypersensitivity to the active ingredients or related compounds.

WARNINGS AND PRECAUTIONS

1. General

2. Appropriate Administration

3. Storage and Handling

4. Use in Specific Populations

5. Laboratory Tests

6. Interaction with Other Drugs

7. Adverse Effects

FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

2. DOSAGE AND ADMINISTRATION

3. CONTRAINDICATIONS

4. WARNINGS AND PRECAUTIONS

5. ADVERSE REACTIONS

6. LABORATORY TESTS

7. DRUG INTERACTIONS

8. USE IN SPECIFIC POPULATIONS

9. INSTRUCTIONS FOR STORAGE AND HANDLING

10. PATIENT DRUG INFORMATION

Table 1: Incidence of Adverse Events (Events Listed at or above 1% in Patients at Risk for These Events)

<table>
<thead>
<tr>
<th>Event</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>2.0%</td>
</tr>
<tr>
<td>Rash</td>
<td>1.5%</td>
</tr>
<tr>
<td>Pruritus</td>
<td>1.0%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>0.5%</td>
</tr>
<tr>
<td>Somnolence</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

For more information, please refer to the full prescribing information.
11. Materials and methods

11.1. Participants

The participants were recruited from the primary care clinics in the region. They were divided into two groups: Group A (control) and Group B (treatment). Group A received a placebo, while Group B received the study medication. The participants were followed for 12 weeks, and the outcomes were assessed at baseline and after 6 and 12 weeks.

11.2. Study protocol

The study protocol was approved by the institutional review board, and all participants provided informed consent. The study was conducted according to the principles of the Declaration of Helsinki.

11.3. Statistical analysis

The data were analyzed using the Wilcoxon signed-rank test for paired samples. The results were considered statistically significant at p < 0.05.

Table 1: Summary of clinical characteristics of participants

<table>
<thead>
<tr>
<th>Group</th>
<th>Age (years)</th>
<th>Gender (M/F)</th>
<th>BMI (kg/m²)</th>
<th>Blood pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>45</td>
<td>30/25</td>
<td>25</td>
<td>120/80</td>
</tr>
<tr>
<td>B</td>
<td>45</td>
<td>30/25</td>
<td>25</td>
<td>120/80</td>
</tr>
</tbody>
</table>

12. Discussion

The results of this study showed that the study medication significantly improved the clinical outcomes in Group B compared to Group A. The findings support the use of the study medication in the management of the disease.

13. Conclusion

In conclusion, the study medication was effective in improving the clinical outcomes in patients with the disease. Further studies are needed to confirm these findings and to explore the mechanisms of action of the study medication.