Antihistaminics are used in symptomatic treatment of rhinitis, sneezing, rhinorrhea, nasal itch etc. However, many of them produce drowsiness and CNS depression. Septilin is a herbomineral preparation. It has shown promising antiallergic activity in cases of rhinitis and is devoid of side effects even after long-term use. Recently the antiallergic activity of Septilin was found to be as effective as that of chlorpheniramine, with a very low incidence of side effects (4%) such as sedation, dryness of mouth and incoordination, as compared to those of chlorpheniramine (28%). This observation prompted us to evaluate the antihistaminic effect of Septilin in healthy human subjects.

Each Septilin tablet contains:
Balasamodendron mukul (Guggul purified) 0.162 g  
Shankh bhasma 32 mg  
Exts. Maharasnadi quath 65 mg  
Tinospora cordifolia 49 mg  
Rubia cordifolia 32 mg  
Emblica officinalis 16 mg  
Moringa pterygosperma 16 mg  
Glycyrrhiza glabra 6 mg

A multiple dose, double-blind, placebo-controlled study was conducted in two parallel groups of 16 male healthy subjects. They were aged between 20-25 years with normal liver and renal function and with no history of allergic disorder or any other drug intake. The study was approved by our local ethical committee and informed written consent was obtained from all the volunteers.

The subjects were randomly allocated to two groups which received either Septilin (3 tablets twice daily in a supervised regimen) or a matched placebo (same dose), daily over a period of 4 weeks. On day 1, the subjects reported at 8.00 a.m. in a fasting state. The histamine wheal test was performed on the forearm by injecting 2 mg of histamine phosphate in 0.1 ml of distilled water by the intradermal route. The erythema and wheal were observed 15 min after the injection and noted by outlining the margins and transferring the impression on white paper first and later to transparent butter paper. The area was measured on a graph paper having sq. mm recording and then calculated.

After performing zero hour test, the assigned preparation (Septilin 3 tablets or matched placebo 3 tabs) was given to the subjects and the histamine test repeated at 2 and 4 hrs, on different areas of the forearm, after a single dose. The same dose was administered at 4.00 p.m. and daily thereafter in a twice daily regimen over the next 4 weeks. The histamine test was performed at weekly interval 2 hours after the morning dose in the same manner as on day 1. The results were analysed using paired t-test.

The zero hour wheal and erythema response in both groups did not differ significantly. A single dose of Septilin did not bring about any significant change at 2 and 4 hours in comparison with placebo. However, on chronic administration, Septilin could cause significant reduction in both wheal and erythema. This effect was evident from day 7, reaching a peak on day 21. The findings on day 28 were comparable to those of day 21 (Table 1).
Table 1: Effect of chronic administration of Septilin on histamine-induced wheal and erythema (Mean ± SE)

<table>
<thead>
<tr>
<th></th>
<th>Day 1</th>
<th>Day 7</th>
<th>Day 14</th>
<th>Day 21</th>
<th>Day 28</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythema (Sq. mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>1190 ± 157</td>
<td>1189 ± 158</td>
<td>1207 ± 160</td>
<td>1193 ± 158</td>
<td>1206 ± 160</td>
</tr>
<tr>
<td>Septilin</td>
<td>1128 ± 146</td>
<td>675* ± 104</td>
<td>602* ± 135</td>
<td>536* ± 132</td>
<td>535* ± 131</td>
</tr>
<tr>
<td>Wheal (Sq. mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>162 ± 15</td>
<td>164 ± 15</td>
<td>170 ± 14</td>
<td>168 ± 17</td>
<td>167 ± 14</td>
</tr>
<tr>
<td>Septilin</td>
<td>160 ± 22</td>
<td>94 ± 9</td>
<td>83 ± 10</td>
<td>78 ± 9</td>
<td>72 ± 10</td>
</tr>
</tbody>
</table>

A single dose of Septilin did not show any significant effect which distinguished it from conventional antihistaminics but on chronic administration it showed antihistaminic activity. The mechanism of action needs further investigation. The gradually developing antihistaminic effect together with the anti-inflammatory and anti-exudative activity suggest that Septilin may be a useful agent in treating chronic allergic disorders.

REFERENCES