Revision of Precautions

Bilastine

December 3, 2019

Therapeutic category
Allergic agents-miscellaneous

Non-proprietary name
Bilastine

Safety measure
Precautions should be revised in the package insert.
Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

<table>
<thead>
<tr>
<th>Current</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Reactions (N/A)</td>
<td>Adverse Reactions Clinically Significant Adverse Reactions Shock, anaphylaxis: Shock or anaphylaxis may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.</td>
</tr>
</tbody>
</table>

N/A: Not Applicable, because the section is not included in the current package insert.