Revision of PRECAUTIONS

Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio-
Haemophilus type b conjugate combined vaccine
(Gobik Aqueous Suspension Syringes)

February 6, 2024

Therapeutic category
Mixed biological preparations

Non-proprietary name
Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio-Haemophilus type b conjugate combined vaccine (Gobik Aqueous Suspension Syringes)

Safety measure
PRECAUTIONS should be revised.
Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

<table>
<thead>
<tr>
<th>Current</th>
<th>Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</td>
<td>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</td>
</tr>
<tr>
<td>Individuals who receive vaccinations and timings of vaccinations This vaccine should be administered to individuals aged 2 months to 60 months after birth. The initial immunization should be started at the ages of 2 months or over and under 7 months after birth, and the vaccine should be administered at intervals of 20 to 56 days as the standard practice. The booster dose should be given between 6 months to 13 months after the end date of the vaccinee’s initial immunization as the standard practice.</td>
<td>Individuals who receive vaccinations and timings of vaccinations This vaccine should be administered to individuals aged 2 months to 90 months after birth. The initial immunization should be started at the ages of 2 months or over and under 7 months after birth, and the vaccine should be administered at intervals of 20 to 56 days as the standard practice. The booster dose should be given between 6 months to 18 months after the end date of the vaccinee’s initial immunization as the standard practice.</td>
</tr>
</tbody>
</table>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.