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Translated by
Pharmaceuticals and Medical Devices Agency



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

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.

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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.

Current	Revision
<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p>Individuals who receive vaccinations and timings of vaccinations This vaccine should be administered to individuals aged 2 months to <u>60</u> 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 <u>13</u> months after the end date of the vaccinee's initial immunization as the standard practice.</p>	<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p>Individuals who receive vaccinations and timings of vaccinations This vaccine should be administered to individuals aged 2 months to <u>90</u> 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 <u>18</u> months after the end date of the vaccinee's initial immunization as the standard practice.</p>

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

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