Published by Ministry of Health, Labour and Welfare 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 (Quintovac Aqueous Suspension Injection)

February 6, 2024

Therapeutic category

Mixed biological preparations

Non-proprietary name

Adsorbed diphtheria-purified pertussis-tetanus-inactivated polio-*Haemophilus* type b conjugate combined vaccine (Quintovac Aqueous Suspension Injection)

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> 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
7. PRECAUTIONS CONCERNING DOSAGE AND	7. PRECAUTIONS CONCERNING DOSAGE AND
ADMINISTRATION	ADMINISTRATION
Individuals who receive vaccinations and timings of vaccinations	Individuals who receive vaccinations and timings of vaccinations
This vaccine should be administered to individuals aged 2	This vaccine should be administered to individuals aged 2
months to 60 months after birth. The initial immunization should	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	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	after birth, and the vaccine should be administered at intervals of
20 to 56 days as the standard practice. The booster dose should	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	be given between 6 months to 18 months after the end date of
the vaccinee's initial immunization as the standard practice.	the vaccinee's initial immunization as the standard practice.

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

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u>