

## To persons desiring a HPV vaccination (CERVARIX for intramuscular injection):

At the time of HPV vaccination (CERVARIX for intramuscular injection), it is necessary to fully grasp the health status of the person to be vaccinated. Please read the explanation below, then fill in the "Screening Questionnaire for HPV Vaccination (CERVARIX)" and undergo a doctor's examination. For minors, a guardian familiar with the health status of the child is requested to fill in the form.

### Prevention of infection with oncogenic HPV-16 and -18 with the HPV vaccine (CERVARIX)

- ① Although CERVARIX cannot avoid infection with all types of oncogenic HPVs, it is expected to prevent infection with HPV-16 and -18.
- ② In patients who have already been infected with an oncogenic HPV before the vaccination, CERVARIX does not eliminate the viruses, delay progression of cervical cancer or precancerous lesions that have already developed, or treat them.
- ③ Even after the vaccination, it is necessary to get regular cervical screening for early detection of lesions caused by carcinogenic HPV types that cannot be prevented with vaccines. Municipalities organize public cervical screening for women aged 20 years or older, once per 1-2 years. If you have any concerns, immediately contact your vaccination facility.

### Effects and adverse reactions of this vaccine

Clinical trials show that CERVARIX has the effect of preventing the infection with HPV-16 and -18 and the development of precancerous lesions in women aged 15-25 years. Although there are no data for girls aged 10-15 years, it is shown that CERVARIX produces antibodies in them as shown in women aged 15-25 years.

Main side effects include pain, erythema and swelling at the injected site, and headache, sometimes associated with general symptoms such as malaise or fever. Possible serious side effects include shock and anaphylaxis (allergic reaction that usually develops within 30 minutes after vaccination associating with breathing difficulty and/or generalized hives), acute disseminated encephalomyelitis (ADEM), and Guillain-Barre syndrome (e.g., numbness in the arms and feet, and/or difficulty with ambulation).

### Persons who must not undergo preventive vaccination:

- (1) Persons with fever (37.5°C or higher).
- (2) Persons clearly suffering from an acute disease.
- (3) Persons who have had an anaphylactic reaction to any component of this vaccine (allergic reaction accompanied by difficulty in breathing or systemic urticaria appearing usually within 30 minutes after inoculation).
- (4) In addition, persons who are judged to be unsuitable for preventive vaccination by the doctor.

### Persons who must consult doctor prior to preventive vaccination:

- (1) Persons with a low platelet count or bleeding tendency.
- (2) Persons with an underlying disease related to the cardiovascular system, kidneys, liver or blood, or a developmental disorder.
- (3) Persons who developed fever or symptom suggestive of allergy, such as systemic rash, within 2 days after a previous preventive vaccination.
- (4) Persons with a history of convulsions (seizures).
- (5) Persons who have been diagnosed with immunodeficiency in the past or have a relative with congenital immunodeficiency.
- (6) Persons who are or may be pregnant.
- (7) Persons who are currently breastfeeding.
- (8) Persons who have had any preventive vaccination in the last month.

### Post-vaccination Cautions

- (1) As fainting may occur after vaccination, please relax in a chair with a backrest at the vaccination facility for about 30 minutes after inoculation. Return home only after no change in physical condition has been verified.
- (2) Avoid strenuous exercise on the day of inoculation and keep the injection site clean. You can take a bath on the day of inoculation.
- (3) If you feel any abnormal reaction at the injection site or change in physical condition after inoculation or if any abnormal symptom such as a high fever occur or if you suffer from convulsions, immediately present at a clinic or hospital for an examination.
- (4) In the event that any adverse health effects arise as a result of inoculation with this vaccine, treatment expenses, etc. may be paid based on the "Adverse Drug Reaction Relief System". For further details, please refer to the Pharmaceuticals and Medical Devices Agency website.

Scheduled Date of Vaccination	/	(dd/mm)	Name of Medical Institution	
At	:	am/pm		

\*If you desire to be vaccinated, fill in the boxes below:

## Screening Questionnaire for HPV Vaccination (CERVARIX)

	Body temperature before interview	°C
Number of Doses	First/Second, Last Vaccination Date:      /      /      (dd/mm/yy)	
Address	TEL No.	
Patient's Name	M F	Birth Date /      /      (dd/mm/yy) Age (      years      months)

Questionnaire for Vaccination	Answer	Doctor's Comment
Have you read and understood the explanation about the vaccination that will be administered today?	No      Yes	
(If today's administration will be the 2nd or 3rd vaccination for you) Have you ever been administered CERVARIX as HPV vaccination?	No      Yes	
Do you currently have any sort of illness? Are you feeling sick today?	Yes If so, please describe in detail. (      )	No
Are you receiving any treatment (e.g., medicines) for the illness?	Yes Name/type of the medicine (      )	No
Have you been ill in the past month?	Yes Disease name (      )	No
Do you have a health problem with heart disease, kidney disease, liver disease, hematologic disease, immune deficiency, or others for which you have consulted a doctor? Where relevant, did the doctor who manages the above disease agree with today's vaccination?	Yes Disease name (      ) No	No Yes
(If the vaccination is for a child) Were there any problems with the child's health at delivery, after birth, or at infant health check?	Yes Describe in specific (      )	No
Have you ever had a seizure (spasm or fit) in the past? Did you have a fever at that time?	Yes At (      ) years old Yes	No
Have you ever had a rash or urticaria (hives or 'nettle rash') as a reaction to medications or food, or become ill after eating certain foods or receiving certain medications?	Yes Food or medication name (      )	No
Have any of your family members or relatives had a serious reaction to a vaccine in the past?	Yes Vaccine name (      )	No
Do you have a family member or relative with a congenital immunodeficiency?	Yes	No
Have any of your family or anyone around you contracted measles, rubella, chickenpox, or mumps in the past month?	Yes Disease name (      )	No
Have you been vaccinated in the past month?	Yes Vaccine name (      ) Date administered:      /      (dd/mm)	No
Have you had a serious reaction to a vaccine in the past?	Yes Vaccine name (      )	No
(Women only) Are you pregnant or possibly pregnant?	Yes	No
(Women only) Are you breastfeeding?	Yes	No
Do you have any questions about today's vaccination?	Yes Describe in specific (      )	No

<b>Doctor's Comment</b> Based on the above answers and the results of interview, I have decided that the patient (can / should not) receive a vaccination today. I have explained to the patient (or the guardians) the information concerning the benefits and side effects of vaccination as well as the Relief System for Sufferers from Adverse Drug Reactions.	<b>Signature or Name and Seal of Doctor:</b> _____
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Having interviewed and explained by the doctor, do you wish to receive a vaccination with the understanding of the benefits and side effects of vaccination and the Relief System for Sufferers from Adverse Drug Reactions? Yes / No	<b>Signature of the Patient or Proxy</b> _____ If proxy signs, describe relationship _____
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Vaccine Name	Vaccination Site, Dosage, and Administration	Institution, Doctor Name, Date Administered
Recombinant adsorbed bivalent human papillomavirus-like particle vaccine (derived from Trichoplasia ni cells) CERVARIX GlaxoSmithKline K.K. Lot No.:	Intramuscular injection, 0.5mL ( R / L )	Institution Doctor Name Date Administered      /      (dd/mm/yy) At      :      am /pm

This screening questionnaire is used to ensure the safety of vaccination. The personal information described here will be used only for screening for vaccination.