

PATIENT CONSENT FORM

The pregnancy registry set up by Sanofi Pasteur MSD aims to collect information on the pregnancy of women vaccinated with Gardasil® (Human Papillomavirus Vaccine [types 6, 11, 16, 18] (Recombinant adsorbed) in order to evaluate the possible effects of this vaccine on pregnant women and on their babies.

Any woman vaccinated with Gardasil® within one month prior (30 days) to, or at any time during the pregnancy will be able to enrol in this registry.

If you agree to enrol in this registry, your doctor will have to fill out a preliminary questionnaire including vaccination information, your past medical history, and your health conditions when declaring your pregnancy.

At the estimated delivery date, a second questionnaire will be forwarded to your doctor in order to obtain information on your pregnancy course, your delivery and on your baby's health.

In order to evaluate the possible long-term adverse events of Gardasil® vaccine on your baby's health, we will ask to the doctor following your baby to fill out a questionnaire on his/her health up until age of six months.

You and your baby will only be identified in the pregnancy registry by your initials and birthdates. Your identity will not be communicated; it will simply allow your doctor to be contacted in order to get information on your pregnancy course and on your baby's health.

Except contrary legal provisions, only appropriate personnel within Sanofi Pasteur MSD and his manufacturer (Merck and Co. Worldwide Product Safety and Epidemiology) as well as the concerned Health Authorities will have access to the information contained in the pregnancy registry.

Your participation in this pregnancy registry as well as any information communicated directly by yourself to Sanofi Pasteur MSD, are entirely voluntary. You are free to reconsider your participation at any time if you wish to.

If you have any questions on this registry or if you wish to reach information concerning you and which were recorded in this pregnancy registry, feel free to contact:

Sanofi Pasteur MSD
Pharmacovigilance department – Pregnancy Registry
8, rue Jonas Salk
69367 LYON Cedex 07 – FRANCE

I undersigned (name, first name) agree to enrol in the pregnancy registry and authorise Sanofi Pasteur MSD to:

- Collect and record information related to my health conditions during pregnancy and my baby up until age of six months, making it possible to determine the existence of possible adverse events following the vaccination,
- Contact my doctor in order to get information via the completed questionnaires, making it possible to determine if adverse events occurred are the consequence of the vaccination or related to any other cause,
- Obtain from my or my baby's doctor additional information contained in my or my baby's medical file in order to make it possible to identify the cause of potential adverse events reported.

Signature

Place, Date

SPMSD Use only Received on: ARISg Number: WAES Number:

Please return this document to
Sanofi Pasteur MSD - Pharmacovigilance department, Pregnancy Registry
8, rue Jonas Salk – 69367 LYON Cedex 07 – France or fax to 0805.858.848