## What is the MENVEO Pregnancy Registry?

The MENVEO Pregnancy Registry is an observational study being conducted in the United States (US) to evaluate pregnancy outcomes in women vaccinated with MENVEO within 28 days prior to conception or at any time during pregnancy. The purpose of the Registry is to collect information on pregnant women and their babies at outcome. The information collected will provide doctors with a better understanding of the effect (if any) of MENVEO exposure during pregnancy.

This Registry is sponsored by GlaxoSmithKline and is managed by Pharmaceutical Product Development (PPD), Inc.

## What are my rights as a participant?

Your participation in this Registry is voluntary following informed consent. You may decide not to participate or you may leave the Registry at any time. If you do decide to be in the Registry, your consent to take part will not end unless you withdraw it. If at any time you do not want to be in the Registry, you may let us know by calling or writing the Registry.

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## Registry Contact Information

**MENVEO Pregnancy Registry**
PPD, Inc.
929 North Front Street
Wilmington, NC 28401-3331

**Toll-free number:**
1-877-413-4759

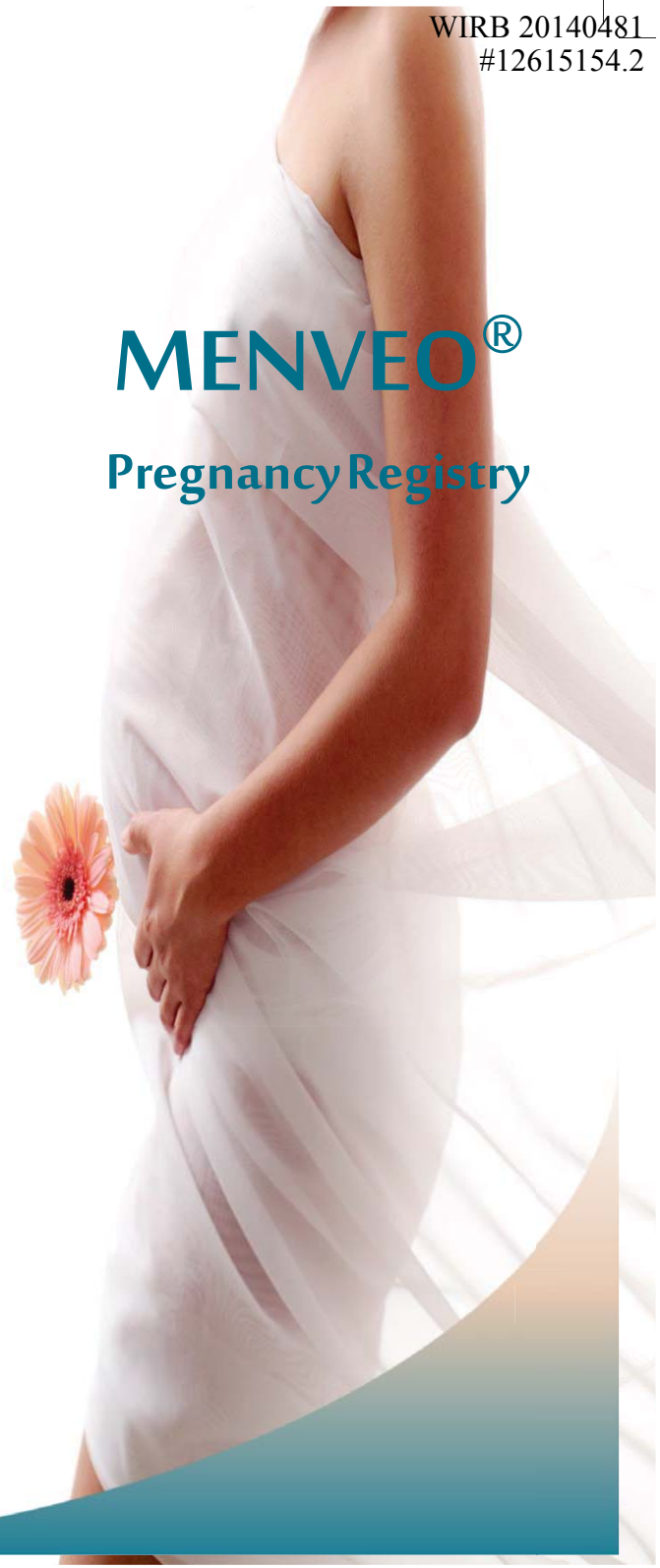
**Toll-free fax number:**
1-866-898-0564

**Email:**
MENVEOPregnancyRegistry.SM@ppdi.com

04/2017

# MENVEO®

## Pregnancy Registry



# MENVEO

## Pregnancy Registry

## How to take part in the Registry?

If you are pregnant and have been vaccinated with MENVEO within 28 days prior to becoming pregnant or at any time during pregnancy, choose one of the following ways to enroll:

- Call the Registry's toll-free number and speak to a Registry staff member (1-877-413-4759)
- Let one of your doctors know you would like to take part in the Registry by showing them this brochure

### For Health Care Providers

Doctors or other health care providers can enroll pregnant women by one of these methods

- Contact the Registry Coordination Center and request a set of registration materials (1-877-413-4759)
- Assist your patient in either contacting the Registry or filling out the Participant Consent to Contact Card

## What does taking part in the Registry involve?

Either the Registry Coordination Center or one of your health care providers will tell you about the Registry. If you are eligible to take part in the Registry, you will be asked to give your consent for the Registry to contact the health care provider seeing you for this pregnancy and the health care provider that vaccinated you with MENVEO. The Registry will ask for information about your medical condition, your general health during pregnancy and your baby's health.

By taking part in the Registry, you will NOT have to:

- Make any extra office visits
- Take any extra medical tests
- Take additional medications

Your privacy will be protected.

### For Health Care Providers

Providers will only be asked to provide information that is routinely collected in the course of usual care and will be contacted at registration, at the end of the 2nd trimester and at pregnancy outcome.

**Registry contact information is provided on the back of this brochure**

## Why should I take part in the Registry?

There is no direct benefit to women (or to their babies) who volunteer to take part in the Registry. Through the Registry, more will be learned about the use of MENVEO during pregnancy. The information could help pregnant women in the future.

The success of the Registry relies on pregnant women and health care providers to report a pregnancy if MENVEO was given within 28 days prior to or at any time during pregnancy.

### For Health Care Providers

There is an expert Scientific Advisory Committee that reviews the Registry data independently of the company that makes and supplies MENVEO. This committee includes experts in:

- Maternal and Fetal Medicine
- Epidemiology
- Pediatrics
- Infectious Diseases
- Teratology

The data is summarized in Registry Reports which are submitted to regulatory agencies annually, and when the study is complete.