

What is the BEXSERO Pregnancy Registry?

The BEXSERO Pregnancy Registry is an observational study being conducted in the United States (US), to evaluate pregnancy outcomes in women vaccinated with **BEXSERO within 30 days prior to their last menstrual period 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 BEXSERO 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.

Registry Contact Information

BEXSERO 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:
BEXSEROPregnancyRegistry.SM@ppdi.com



BEXSERO Pregnancy Registry

BEXSERO

Pregnancy Registry

How to take part in the Registry?

If you are pregnant and have been vaccinated with BEXSERO within 30 days prior to your last menstrual period 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 and request a set of registration materials (1-877-413-4759)
- Assist your patient in contacting the Registry

What does taking part in the Registry involve?

Either the Registry staff 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 collect information about your medical condition, your general health during pregnancy and your baby's health from the health care provider seeing you for this pregnancy and the health care provider that vaccinated you with BEXSERO.

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 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 BEXSERO 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 BEXSERO was given within 30 days prior to their last menstrual period 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 Bexsero. This committee includes experts in:

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

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