What is the TYSABRI® (natalizumab) Pregnancy Exposure Registry?
The TYSABRI Pregnancy Exposure Registry is a voluntary, observational study sponsored by Biogen Idec and Elan. The purpose of the Registry is to study the outcomes of pregnancy in women who were exposed to TYSABRI within 90 days prior to the first day of the last menstrual period or at any time during their pregnancy. Patients will be followed in the Registry throughout their pregnancy. Information will also be collected from the patient and health care provider within 4 weeks of delivery and from the baby's doctor at 8 to 12 weeks after the arrival of the baby. Additional follow up may be performed as needed. It is anticipated that approximately 300 pregnancies will be registered prospectively in the TYSABRI Pregnancy Exposure Registry, where the outcome of the pregnancy is unknown at the time of enrollment.

There are no adequate and well-controlled studies of TYSABRI in pregnant women. TYSABRI should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Tell your health care provider if you are pregnant or plan to become pregnant.. Registry data supplement other sources of information and assist clinicians and patients in weighting potential risks and benefits of treatment.

How do I enroll? How are data collected by the Registry?
After your pregnancy is confirmed, your doctor will invite you to join the TYSABRI Pregnancy Exposure Registry.
Your doctor may call to enroll you or you may enroll yourself in the TYSABRI Pregnancy Exposure Registry by calling the Coordinating Center at a toll-free number: **1-866-831-2358**. You can enroll in the Registry at any time during your pregnancy. Ideally, the Registry would like to enroll women as early in their pregnancy as possible before they have any prenatal testing performed, but we welcome you to enroll at any time during your pregnancy.

You will be followed throughout your pregnancy and after your baby is born if needed. Information will be collected from your baby's physician about your baby's birth and health at 8 to 12 weeks of age and beyond if necessary. The Coordinating Center will serve as the primary data collection center for the duration of this Registry. Throughout the Registry, the Coordinating Center will maintain toll-free phone and fax lines to facilitate patient enrollment, data collection, and data queries. Your participation in this Registry is voluntary. If at any time you decide to withdraw from the Registry, please notify your physician or the Coordinating Center. From that time on, neither you nor your physician will be contacted by the Coordinating Center.

All of the information collected in the TYSABRI Pregnancy Exposure Registry will be kept confidential according to the requirements of Health Insurance Portability and Accountability Act (HIPAA) and other international privacy statutes and regulations.

What can I expect?
You will be contacted via telephone by the Coordinating Center at the time of registration and once per trimester. You will be asked by the Coordinating Center to give consent to be enrolled in the Registry. In addition, your physician who is caring for you during pregnancy will be contacted between the 6th to 7th month of your pregnancy and, again, within 4 weeks after your estimated delivery date. The Coordinating Center will also contact you and/or your baby's physician when the baby is 8 to 12 weeks of age and additional information may be collected past this time point, if needed. The following information will be collected from you each trimester:

- Any changes in the contact information you provided
- Any changes in the status of your pregnancy

The TYSABRI Pregnancy Exposure Registry is an observational program. No physician visits are required for you to participate in the TYSABRI Pregnancy Exposure Registry. There are no special tests needed and no treatment therapies will be provided. You will receive the standard treatment or care usually given by your treating physician.

How will the data be analyzed and reported?
Information about your health collected while you are in the TYSABRI Pregnancy Exposure Registry will be kept in confidence and in accordance with privacy statutes and regulations (e.g., HIPAA). All information that the Coordinating Center receives will be stored in a secure database and patient confidentiality will be respected. As is customary, the sponsors of the program, Biogen Idec and Élan may be required to provide certain safety information to the Food and Drug Administration (FDA) including personal medical information. In any presentation of the results of the Registry at meetings or in publications, your identity will remain anonymous and confidential.

How will the information from the TYSABRI Pregnancy Exposure Registry be used?
The Registry is the primary source of information to evaluate the outcomes of pregnancy in women who were exposed to TYSABRI within 90 days prior to the first day of the last menstrual period or at any time during their pregnancy. Registry data supplement other sources of data and assist clinicians and patients in weighing potential risks and benefits of treatment.

How can I get more information? E-mail, call, or fax:
Registry Coordinating Center
Tel: 1-866-831-2358 Fax: 1-866-718-6927
E-mail: LSKC.BiogenIdec.TYSABRI@unitedbiosource.com
Please see full Prescribing Information, including Boxed Warning, and Patient Medication Guide at www.TYSABRI.com
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