MERCK
Research Laboratories

Restricted Confidential
limited access

Consent Form for the Merck Pregnancy Registry for JANUVIA® (sitagliptin phosphate) and JANUMET® (sitagliptin phosphate/metformin hydrochloride)

You or your health care provider notified the Merck Pregnancy Registry for JANUVIA® and JANUMET® that you had received JANUVIA® or JANUMET® at some time during your pregnancy. The Merck Pregnancy Registry is trying to collect as much information as possible to give health care providers information on the use of this vaccine during pregnancy. We are asking you to please consider enrolling in the Registry.

Although there is no immediate benefit to you from participating, the information we obtain from the registry will be sent out to physicians, nurses, and genetics counselors to help them and patients like you evaluate the risk, if any, associated with the use of the drug during pregnancy. Unless required by law, only Merck & Co., Inc. and government regulatory agencies will have access to confidential information which identifies you by name. Names will not be released to the public and will only be used by Merck & Co., Inc. to obtain follow-up information from you, your health care providers, and your baby's health care providers.

If you agree to participate, you or your doctor will fill out a questionnaire asking about your use of the medication. Other questions will ask about this pregnancy and your previous pregnancies. Around the time you are due to deliver the baby, a second questionnaire will be sent to your doctor(s) asking about your pregnancy, labor and delivery, and the health of your baby. We might ask for copies of your or your baby's medical records. In order to explore the long-term health of babies whose mothers received this medication during pregnancy, we may request information from the baby's pediatrician for up to two years after the birth. Again, unless required by law, only Merck & Co., Inc. and government regulatory agencies will have access to information which identifies you by name.

Your participation in the Pregnancy Registry and in providing us with information is entirely voluntary, and your refusal to participate will not cause any change in your medical care. You can decide not to participate further at any time, even if you agreed to participate at first. If you have any questions about the Registry or your rights as a participant, you can call Kris Shields at the Merck Pregnancy Registries at 800-986-8999 to obtain additional information.

Your signature below means that you agree to allow us to: 1) enroll you in the Pregnancy Registry, 2) contact your and your child's health care providers, and 3) to obtain copies of your medical records related to this pregnancy and copies of your child's medical records for up to two years of age. Your signature allows your and your child's health care providers to accept a copy of this form as if it were the original.

❑ Yes, I agree to participate in the Pregnancy Registry for JANUVIA® and JANUMET®.

❑ No, I do not agree to participate in the Pregnancy Registry for JANUVIA® and JANUMET®.

_____
Signature of participant Date

_____
Signature of witness Date

_____
Signature of parent/guardian if participant is under 18 Date

Note: Consent form is available in Spanish upon request; call 800-986-8999.

Pediatrician Name	Address / Phone Number

Merck Use Only **WAES Number** _____

Return form to: Merck Pregnancy Registries, Worldwide Product Safety/Clinical Risk Management & Safety Surveillance, P.O. Box 4, WP97A-285, West Point, PA 19486 or Fax to: (215) 993-1220