

# MotherToBaby Launches New Observational Study of Mepolizumab (Nucala®) in Pregnancy

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BRENTWOOD, TN – MotherToBaby Pregnancy Studies, conducted by the Organization of Teratology Information Specialists (OTIS), has launched a new observational study of mepolizumab (Nucala®) in pregnancy, a new medication for the treatment of severe asthma. This study aims to provide crucial information on the safety of this medication in pregnancy by following asthmatic women during their pregnancy and following their child up to one year of age. Given that untreated asthma can put both the mother and pregnancy at risk, the need for rigorous and ongoing research of new medications and their effects during pregnancy becomes vitally important. This study will expand efforts to better understand safety of asthma medications in pregnancy.

Mepolizumab (Nucala®), launched by GlaxoSmithKline (GSK) in November 2015, was the first IL-5 inhibitor approved by the U.S. Food and Drug Administration (FDA) for as an add-on treatment for severe asthma with an eosinophilic phenotype. Similar to inhaled steroids, mepolizumab provides a preventative approach to asthma control; it is thought to act by inhibiting interleukin 5 (IL-5), a group of proteins and signal molecules produced by white blood cells. This may decrease inflammation in the lungs and the number of subsequent severe asthma attacks in persons with eosinophilic asthma. Mepolizumab is administered as an injection under the skin (subcutaneously) once every 4 weeks. It is not intended to treat active asthma symptoms.

“We know that asthma in pregnancy, especially poorly controlled asthma, is associated with higher rates of pregnancy complications, like placental problems, premature delivery, and low birth weight. With this reality, it is especially important that a woman’s asthma be carefully managed prior to and during a pregnancy,” said Christina Chambers, PhD, MPH, MotherToBaby Pregnancy’s Studies lead investigator and world-renowned perinatal epidemiologist at UC San Diego. “Yet medications that are newly approved by the FDA have little to no information about how safe they are for a pregnant woman and her developing baby. Our research aims to fill this critical gap.”

In addition to mepolizumab, MotherToBaby Pregnancy Studies are also enrolling pregnant women who are using other medications for the treatment of their asthma including, but not limited to albuterol, formoterol, salmeterol, and/or inhaled steroids, as well as pregnant women who do not have asthma. These studies are coordinated by the University of California, San Diego, and are in collaboration with the American Academy of Allergy, Asthma & Immunology as part of the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS).

Women who are pregnant and who reside in the U.S. or Canada may be eligible to participate. Participants are not asked to take or alter any medications, do not need to travel, and are not asked to make any changes to their normal routine.

To join or for more information on MotherToBaby Pregnancy Studies, call toll-free 877.311.8972, visit [MotherToBaby.org](http://MotherToBaby.org) or email [MotherToBaby@ucsd.edu](mailto:MotherToBaby@ucsd.edu).

If you are pregnant or planning a pregnancy and have questions about asthma and the medications used to treat asthma in pregnancy, **MotherToBaby Fact Sheets** are available in both English and Spanish and can be downloaded for free. MotherToBaby experts are also available to provide free personalized risk assessments via phone, email, text, or live-chat.

## More about MotherToBaby

MotherToBaby is the nation’s leading authority and most trusted source of evidence-based information on the safety of medications and other exposures during pregnancy and while breastfeeding.

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) Office of Women’s Health have recognized OTIS and MotherToBaby as a recommended resource for information on exposures during pregnancy and lactation.

**Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at [MotherToBaby.org](https://www.MotherToBaby.org).**

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