

## Women can continue certolizumab during breastfeeding



Only very small amounts of certolizumab cross into human breastmilk.

### INTRODUCTION

Chronic inflammatory diseases include rheumatoid arthritis, ankylosing spondylitis, axial spondyloarthritis, psoriatic arthritis, and Crohn's disease. These diseases often affect women in their childbearing years, and many experience their disease getting worse after their baby is born.

Treatment of these conditions often uses biologic drugs called monoclonal antibodies, and it has been reported that these may cross into a woman's breastmilk. Certolizumab (brand name CIMZIA) is a biologic monoclonal antibody, but the molecule is different to other biologic drugs because it does not have something in its structure called an *Fc region*, which changes the way it interacts with cells in the body.

### WHAT DID THE AUTHORS HOPE TO FIND?

The authors wanted to see how much certolizumab crosses into breastmilk so that they could advise women about the safety of taking certolizumab while breastfeeding.

### WHO WAS STUDIED?

The study looked at 17 women who were breastfeeding and taking certolizumab for their autoimmune disease. Some women had inflammatory bowel disease and others had inflammatory arthritis such as rheumatoid arthritis.

### HOW WAS THE STUDY CONDUCTED?

This was a prospective, multicentre study. This means that the women were observed over a period of time and measurements were taken during this period. Everyone involved has already taken at least three doses of certolizumab before the study started. A nurse came to their home to help the women collect milk samples at set times. The first sample was collected right before taking their certolizumab and the rest were collected every other day for the next 2 weeks. These milk samples were frozen and sent to the lab, where the authors measured the amount of certolizumab.

### WHAT WERE THE MAIN FINDINGS OF THE STUDY?

The authors found that women either had no detectable certolizumab or tiny amounts of certolizumab in their breastmilk over the 2 weeks after taking a certolizumab dose. They compared the amounts found in the breastmilk to the amount that a woman would take in a single dose and found that the breastmilk contained about 0.15% of the adult dose. Because certolizumab is not easily absorbed when taken orally, it is not likely that it would find its way into a baby's system if very small amounts were present in the mother's breastmilk.

### ARE THESE FINDINGS NEW?

Yes. There have been some reports about the transfer of other monoclonal antibody medicines into breastmilk, but there was no reliable data specifically for certolizumab. In addition, unlike other studies, this one used a very sensitive measure of the certolizumab and a nurse-monitored collection schedule with multiple samples to ensure that even very low levels were captured.

### WHAT ARE THE LIMITATIONS OF THE STUDY?

The authors looked at samples from only 17 women, which is a small number for a study. However, the results were very consistent, and the authors do not think that they would see a different result if more women were included.

Additionally, the study did not collect blood samples from the babies to see if they had certolizumab in their blood. The decision was made not to collect blood from the babies as this would have been traumatic for the child and the parent, and the regulatory authorities involved in the study design did not think there was any need to do this.

### WHAT DO THE AUTHORS PLAN ON DOING WITH THIS INFORMATION?

The authors are letting rheumatologists, obstetricians, paediatricians, and women eligible to receive certolizumab know that this medicine has very limited, if any, transfer into breastmilk and that they consider it safe to take while breastfeeding. Given the health and emotional benefits that mothers and babies can get from breastfeeding this is a great step forward for women living with these challenging diseases, if also the cost of certolizumab will be comparable to biosimilars. The authors have also recently completed a study of certolizumab transfer across the placenta to add to our knowledge about safety during pregnancy. The manuscript for that study is currently under review.

### WHAT DOES THIS MEAN FOR ME?

If you have an inflammatory disease for which you are taking certolizumab, your doctor may advise that you can continue taking your medicine while you are breastfeeding your baby.

It is important that you do not stop taking your medicine or change your dose yourself, so if you have any concerns you should speak to your doctor.

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Date prepared: November 2017

Summary based on research article published on: 9 October 2017

**From:** Clowse, MEB. *et al.* Minimal to No Transfer of Certolizumab Pegol into Breast Milk: Results from CRADLE, a Prospective, Postmarketing, Multicenter, Pharmacokinetic Study. *Ann Rheum Dis* 2017;76:1890–1896. doi: 10.1136/annrheumdis-2017-211384

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