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Tocilizumab

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CASRN: 375823-41-9

Drug Levels and Effects

Summary of Use during Lactation

Only small amounts of tocilizumab were detected in breastmilk after intravenous doses in several mothers. It is also likely to be partially destroyed in the infant's gastrointestinal tract and absorption by the infant is probably minimal.[1] A few mothers have breastfed their infants with undetectable infant serum levels and no reported adverse effects. Several international guidelines have stated that the drug is a low risk to the nursing infant and acceptable to use during breastfeeding.[2-4] Waiting for at least 2 weeks postpartum to resume therapy may minimize transfer to the infant.[5]

Drug Levels

Maternal Levels. A woman with rheumatoid arthritis resumed tocilizumab at 5 weeks postpartum at a dose of 400 mg intravenously every month. Breastmilk concentrations were determined at 13, 18 and 22 weeks postpartum. The highest tocilizumab concentrations in milk occurred 3 days after the injection and was 68.2 mcg/L. The lowest concentration was <0.2 mcg/L at 34 days after the dose. Another mother resumed monthly tocilizumab 400 mg intravenously 9 days postpartum. Breastmilk concentrations were measured after the doses at 35 and 49 weeks postpartum. The highest concentrations occurred 3 days after the injection at 148.2 mcg/L and fell to 9 mcg/L after 28 days.[6]

A woman was treated for adult onset Still's disease with tocilizumab 400 mg every 4 weeks, prednisolone 5 mg daily and tacrolimus 2 mg daily throughout pregnancy. The tocilizumab concentration in milk at 5 days postpartum (32 days after the previous dose) was 3.4 mcg/L. Another dose was given at 6 days postpartum. At about 19 hours later the milk level was 55.4 mcg/L; at 2.8 days after the dose the milk level was 215 mcg/L; at 18 days after the dose, the milk level was 70.4 mcg/L; at 28 days after the dose and before the next dose, the level was 3.8 mcg/L. Another dose was given on day 28. At about an hour after this dose the milk level was 48 mcg/L; 3 days later, the milk level was 205 mcg/L; at 11 days after the dose, the milk level was 127 mcg/L; at 17 days after the dose it was 65 mcg/L, and at 28 days after the dose it was 4.9 mcg/L.[7]

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The same authors measured trough tocilizumab concentrations in four other Japanese women with rheumatoid arthritis receiving the drug 400 mg every 4 weeks, comparing dried milk spots and liquid milk. The highest milk levels were reported on the day 3 sample and ranged from about 70 to 200 mcg/L. Levels fell to low to undetectable levels over the 28-day period. [8]

A Japanese woman was treated during pregnancy with subcutaneous tocilizumab 162 mg every 2 weeks for rheumatoid arthritis. Her last dose was 24 days before delivery. A milk level obtained 2 days after delivery contained 650 mcg/L of tocilizumab, which was 11% of the concentration in maternal blood 1 day prior to delivery.[9]

A woman with Takayasu arteritis was receiving tocilizumab 162 mg subcutaneously every 2 weeks. She collected breastmilk at 5 unspecified times during therapy. All milk samples contained between 3 and 6 mcg/L of tocilizumab.[10]

A Japanese woman with rheumatoid arthritis was receiving tocilizumab until 14 weeks of gestation. The drug was discontinued until 7 days postpartum when a dose of 350 mg of tocilizumab was administered. Tocilizumab colostrum concentrations ranged from 0.39 mg/L shortly after the dose to 0.02 mg/L at 3 days after the dose.[11]

Infant Levels. A woman was treated for adult onset Still's disease with tocilizumab 400 mg every 4 weeks, prednisolone 5 mg daily and tacrolimus 2 mg daily throughout pregnancy. She breastfed almost exclusively postpartum while tocilizumab was continued. The concentration in the umbilical cord blood was 683 mcg/L at delivery 28 days after the previous tocilizumab dose. Even though the infant was almost completely breastfed, the tocilizumab concentration in the infant's serum 5 days after delivery decreased to 177 mcg/L. By 4 weeks after delivery, tocilizumab was not detectable in the infant's serum. Another dose of tocilizumab was given at 28 days postpartum. At 55 days postpartum, tocilizumab was not detected in the infant's serum.[6]

Effects in Breastfed Infants

A pregnancy registry in Japan reported that two mothers resumed tocilizumab therapy while nursing their infants. No adverse events were reported in the infants, but details regarding extent of nursing, infant age, etc. are lacking.[12]

Two women in Japan were treated with intravenous tocilizumab 400 mg monthly for rheumatoid arthritis while they reportedly breastfed their infants exclusively for 9 and 11 months, respectively. Neither infant experienced any adverse effects from the drugs and received all routine immunizations, including BCG without any adverse consequences.[6] It is possible that these two mothers are the same as those reported above.

Three women with rheumatoid arthritis became pregnant while taking tocilizumab. The drug was stopped for the remainder of the pregnancy, but resumed (dose not stated) postpartum. They breastfed their infants (extent not stated). No infants had any adverse effects during the first year.[12]

Three Australian women with rheumatoid arthritis were treated with tocilizumab monotherapy postpartum while taking tocilizumab (dosage not stated) and breastfeeding (extent not stated). None of their infants had any adverse outcomes at 1 year of age.[13]

A woman was treated for adult onset Still's disease with tocilizumab 400 mg every 4 weeks, prednisolone 5 mg daily and tacrolimus 2 mg daily throughout pregnancy and postpartum. She breastfed almost exclusively postpartum while tocilizumab was continued every 4 weeks. Her infant developed no serious infections and demonstrated no developmental delay as of 6 months of age. The infant's routine childhood vaccinations included Haemophilus influenzae type b conjugate, hepatitis B, diphtheria, pertussis, tetanus, inactivated polio, and 13-valent pneumococcal polysaccharide vaccines. No live vaccines were given for the first 6 months postpartum. No adverse effects such as serious infections or immune reactions were seen.[7]

A Japanese woman with rheumatoid arthritis was receiving tocilizumab until 14 weeks of gestation. The drug was discontinued until 7 days postpartum when a dose of 350 mg of tocilizumab was administered. Additional doses were apparently administered monthly thereafter, although the paper is not clear on this point. Her infant was mainly breastfed with occasional additional formula for 6 months. He developed no serious infections and there was no evidence of developmental delay. He received the *Haemophilus influenzae* type b conjugate, hepatitis B, diphtheria-pertussis-tetanus-inactivated polio, and 13-pneumococcal polysaccharide vaccines with no adverse effects. Live vaccines, including the rotavirus and BCG vaccines, were administered at 6 months of age with no adverse effects.[11]

A national prospective registry of patients with rheumatic diseases who were treated with biological DMARDs was conducted in Spain. One whose mothers were taking tocilizumab was breastfed (extent not stated) with no mild or severe adverse events reported in the infant.[14]

Effects on Lactation and Breastmilk

Relevant published information was not found as of the revision date.

Alternate Drugs to Consider

(Rheumatoid Arthritis) Adalimumab, Certolizumab Pegol, Etanercept, Infliximab

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Substance Identification

Substance Name

Tocilizumab

CAS Registry Number

375823-41-9

Drug Class

Breast Feeding

Lactation

Milk, Human

Antibodies, Monoclonal, Humanized

Antirheumatic Agents