

Agent Number 3387 Cetirizine

Last Updated 11/24/2022

Agent Summary

Quick take: Based on experimental animal studies and reported human experience, cetirizine and levocetirizine are not believed to increase the risk of adverse pregnancy outcome.

Cetirizine, an antihistamine, is a metabolite of hydroxyzine [#1101](#). Brand names include Zyrtec (8), Reactine, Alleroff, and Certex-24. The active enantiomer, levocetirizine, is marketed as Xyzal (9).

Experimental animal development

Administration at up to 40, 180, and 216 times the human dose in pregnant mice, rats, and rabbits, respectively, did not produce an increase in congenital malformations in the offspring. Levocetirizine did not increase abnormal pregnancy outcome in rats or rabbits at 300-400 times the human dose (9). The prevalence of malformations was not increased among the offspring of pregnant rats or rabbits treated with up to 500 times the maximum human dose of cetirizine (1).

Human pregnancy reports

In human births with first trimester exposure to cetirizine there were no increases in spontaneous or therapeutic abortion, stillbirth, birth defects, abnormal birth weight, or abnormal gestational age at delivery (2-5,11). Among 917 pregnancies with exposure to cetirizine the prevalence of malformations was similar to that in the general population (6). No association was found between cetirizine use during pregnancy and facial clefts or hypospadias (7). Among 228 pregnancies with cetirizine exposure there was no increase in adverse pregnancy outcomes including malformations (12). Most of the exposures occurred

during the first trimester. Cetirizine was associated in a case-control study with truncus arteriosus and tetralogy of Fallot, although the associations may have been influenced by multiple comparisons (13).

Lactation

Preclinical studies reported in the product labeling found decreased weight gain in pups nursed by mice given 40 times the human dose level of cetirizine (9). About 3% of the maternal dose was detectable in the milk of dogs. The labeling stated that human milk contained cetirizine, but information on milk concentrations was not supplied. Although the labeling stated that use in nursing mothers is not recommended, we have not located data to permit an estimate of human risk, if any, from such exposure. A case report described a mother who was taking sodium oxybate [#3838](#) and cetirizine, among other agents, and successfully nursed for 6 months with normal growth in the infant (10). Milk concentrations were estimated to expose infants to 1.77% of the weight-adjusted maternal dose (14). Three nursing mothers taking cetirizine did not report adverse effects in their infants. Among 228 human milk samples, the cetirizine concentration was 0.65-65 ng/mL (15).

Reproduction

According to the product labeling, cetirizine did not impair fertility in mice at up to 64 mg/kg/day, about 26 times the human dose on a surface area basis (8).

Selected References

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