

## Safety of 2<sup>nd</sup> Generation Antihistamines in Pregnancy

### Antihistamines in Pregnancy 1<sup>st</sup> Trimester H1 2<sup>nd</sup> Generation Antihistamines Live Birth Data

H1 Antihistamine Study Drug (FDA Pregnancy Category)	Ref	Type Study	Study group (n)	Control group (n)	Congenital Malformations N/S=not significant RR is vs. Control				Cardiac	Hypospadias	Spontaneous Abortion	
					Specific H1 %	RR(CL)	All H1 %	Control %			Specific H1 %	Specific H1 %
Cetirizine (B)	<sup>677</sup>	Birth Registry	917	403,545	3.95% (NS)	1.22 (.89, 1.69)	3.4 5%	3.16%	1%	.4%		
Cetirizine (B)	<sup>678</sup>	Prospective	33	38	Maj. 0% Minor 6%	1.15 (.17, 7.73)		Major 0% Minor 5%			18% (NS)	2.6%
Loratadine (B)	<sup>677</sup>	Birth Registry	1769	408,545	3.4% (NS)	1.05 (.38, 1.34)	3.4 5%	3.16%	.5%	.4%		
Loratadine (B)	<sup>679</sup>	Prospective	140	149	3.5% (NS)	.93 (.48, 1.79)		4%			13% (NS)	8%
Loratadine (B)	<sup>680</sup>	Prospective	175	844	Major 2.3%	.77 (.27, 2.19)	4%	3%			11%	7.2%
Terfenadine (C)*	<sup>677</sup>	Birth Registry	1162	408,545	3.22% (NS)	.98 (.72, 1.35)	3.4 5%	3.16%				
Terfenadine (C)*	<sup>681</sup>	Prospective Multicenter	118	118	Major 0%	.57 (.06, 5.39)		2%				
Fexofenadine **(C)	No Studies											

\* No longer available

\*\* The active metabolite of terfenadine