

Ribavirin Pregnancy Registry
Instructions for completing the
PEDIATRIC BIRTH DEFECT SUMMARY FORM

PEDIATRIC PROVIDER

General Information: Provide dates in the ddmonyyyy format (e.g. January 1, 2004 is written 01Jan2004).

1. Date form initiated or update information (Birth Defect diagnosis and form completion)

- If there are multiple outcomes (e.g., twins, triplets) provide details for each outcome. Make copies of this page or indicate the information for each outcome.
- *Note: report period (at outcome, at six months or at twelve months).*
- Indicate whether birth defect was diagnosed by a specialist (specify specialty, by number, person completing form and date form completed)

2. Birth Defects

- List the structural birth defect(s).
- Indicate if the defect was attributed to ribavirin therapy (“yes”, “no”, or “unknown”).
- Indicate other factors that may have contributed to the specific birth defect. (e.g., maternal age may be a contributing factor for Down Syndrome).
- Indicate age (in months) when the defect was noted.
- Provide updated information on defects previously reported (at six and twelve months)

The Registry is not designed to monitor all types of events that might occur during pregnancy, labor and delivery, or other neonatal or postnatal events other than defects. If such events occur, the reporter is encouraged to contact the manufacturer of the individual product and/or FDA. FDA can be reached by faxing the information to 800-FDA-0178 or at <http://www.fda.gov/medwatch/>.

**RIBAVIRIN PREGNANCY REGISTRY
PEDIATRIC BIRTH DEFECT SUMMARY FORM**

Fax to: 800-800-1052
Ribavirin Pregnancy Registry
1011 Ashes Drive, Wilmington, NC 28405

FOR OFFICE USE ONLY

Page 1 of 2

Registry ID _____

HCP ID _____ Baby ID _____

Date Information Received ____/____/____ Phone

Patient (Infant) Name: _____

1. DATA FORM INITIATED OR UPDATE INFORMATION (Birth defect diagnosis and form completion):

Report Period <i>(note last form chk'd)</i>	Birth defect diagnosed by specialist	If yes, specify specialty (by code #)			Form Completed by	Date Completed <i>(dd mmm yyyy)</i>
		1. Cardiologist 2. Dysmorphologist/ Teratologist 3. Family Medicine	4. Maternal Fetal Medicine 5. Midwife 6. Neonatologist 7. Ob/Gyn	8. Pediatrician 9. Radiologist 10. Other, specify		
<input type="checkbox"/> 1) At Outcome	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No	_____	_____	_____	_____	_____
<input type="checkbox"/> 2) At 6 months	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No	_____	_____	_____	_____	_____
<input type="checkbox"/> 3) At 12 months	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No	_____	_____	_____	_____	_____

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2. BIRTH DEFECTS (complete only if birth defects are noted)

Birth defect <i>(list birth defect)</i>	Was the defect attributed to ribavirin therapy? 1 = yes 2 = no 3 = unknown	Other factors that may have contributed to this outcome 1 = unknown 2 = other, specify	Age <i>(in months, when defect was noted)</i>	Information at 6 months <i>Update on any changes in birth defects previously identified (e.g., resolved without intervention, surgery, etc.)</i>	Information at 12 months <i>Update on any changes in birth defects previously identified (e.g., resolved without intervention, surgery, etc.)</i>
1.					
2.					
3.					
4.					

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**Ribavirin Pregnancy Registry
Pediatric Birth Defects Summary Form**

Registry ID _____ (OFFICE USE ONLY)

Patient (Infant) Name: _____

2. BIRTH DEFECTS (Continued)

	Birth defect <i>(list birth defect)</i>	Was the defect attributed to ribavirin therapy? <i>1 = yes 2 = no 3 = unknown</i>	Other factors that may have contributed to this outcome <i>1 = unknown 2 = other, specify</i>	Age <i>(in months, when defect was noted)</i>	Information at 6 months	Information at 12 months <i>1 = unknown 2 = other, specify</i>
5.						
6.						
7.						
8.						
9.						
10						
11						

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