

## ***Ribavirin Pregnancy Registry***

### **Instructions for completing the MALE SEXUAL PARTNER (father of the baby) DIRECT RIBAVIRIN EXPOSURE AND FAMILY HISTORY**

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

#### **1. Ribavirin Therapy During Exposure Period**

- **Med Code:** Indicate 1-12
- **Total Dose:** Provide the total dose and interval (day, wk) with units (e.g., ribavirin 40 mg/day).
- **Route:** Provide the code 1=oral tablet 2=oral capsule, 3=sub-Q (subcutaneous), 4=IM (intramuscular), 5=Other (If other, specify route.)
- **Date Treatment Began:** Indicate the date therapy began for each course.
- **Date Treatment Stopped:** Indicate the date therapy stopped for each course or check box indicating that therapy was ongoing

#### **2. Frequency of Female Partner Exposure**

Indicate when was the first time the pregnant partner was exposed to ribavirin (i.e., unprotected sexual intercourse within six months prior to the pregnancy)?

Indicate frequency that the male sexual partner has unprotected sexual intercourse with the pregnant female (multiple times a week, once a week, once, every 2 weeks, once a month, not at all or other, specify)

#### **3. Paternal (Father of Baby) History**

3.1-3.6 If the father of baby has fathered children from a previous relationship, indicate the number of previous pregnancies and, of these, the number of live infants, spontaneous abortions, stillbirths, elective abortions, and defects.

3.7 **Paternal Family History of Birth Defects:** Indicate if the father of baby has a family history of birth defects.

Directly Exposed Male Sexual Partner and/or the Prescribing HCP

---

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 birth 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  
MALE SEXUAL PARTNER  
(FATHER OF THE BABY) DIRECT EXPOSURE & FAMILY HX**  
Fax to: 800-800-1052  
Mail to: Ribavirin Pregnancy Registry  
1011 Ashes Drive, Wilmington, NC 28405

FOR OFFICE USE ONLY:  
Registry ID \_\_\_\_\_ Page 1 of 2  
Registration date \_\_\_\_\_  Phone  
1<sup>st</sup> Tri. date recvd \_\_\_\_\_  Phone  
2<sup>nd</sup> Tri. date recvd \_\_\_\_\_  Phone  
At outcome date recvd \_\_\_\_\_  Phone

Directly Exposed Male Sexual Partner and/or the Prescribing HCP

Male Log ID: \_\_\_\_\_ Patient Name: \_\_\_\_\_ (if authorization received)

**1. RIBAVIRIN THERAPY DURING EXPOSURE PERIOD (INCLUDING INTERFERON)**

1. Use the med. codes below for medication. If not coded, **Specify Medication.**
- |  |  |
|--|--|
| 1. REBETOL® (ribavirin)                                  | 7. interferon (type of interferon unknown) |
| 2. COPEGUS® (ribavirin)                                  | 8. RIBASPHERE® (ribavirin)                 |
| 3. REBETRON® (Rebetol + Intron A)                        | 9. Ribavirin (Sandoz)                      |
| 4. ribavirin (trade name unknown)                        | 10. Ribavirin (Teva)                       |
| 5. peginterferon alpha (generally given 1 time per week) | 11. Ribavirin (Zydus)                      |
| 6. interferon alpha (generally given 3-7 times per week) | 12. Ribavirin (Aurobindo)                  |

2. In the following table, describe each course or change in route for each applicable therapy

Med. Code (1-12) or if no code indicated, please write medication name	Total Dose please indicated dose with units/interval (e.g., mg/day or mcg/wk)	Route (enter code) 1 = oral tab 2 = oral cap 3 = sub-Q 4 = IM 5 = Other (specify)	Date Treatment Course Began (ddmmyyyy)	Date Treatment Course Stopped (ddmmyyyy)	Ongoing (✓ if ribavirin therapy continuing)
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>
					<input type="checkbox"/>

**2. FREQUENCY OF FEMALE PARTNER EXPOSURE**

- 2.1 When was the first time the pregnant partner was exposed to ribavirin (i.e., unprotected sexual intercourse within six months prior to the pregnancy)? \_\_\_\_\_ (date)  
dd mon yyyy
- 2.2 How often does the male sexual partner have unprotected sexual intercourse with the pregnant female?
- <sub>1</sub> Multiple times a week   <sub>2</sub> Once a week   <sub>3</sub> Once every 2 weeks  
<sub>4</sub> Once a month   <sub>5</sub> Not at all   <sub>6</sub> Other, specify \_\_\_\_\_

**3. PATERNAL (FATHER OF BABY) HISTORY**

Pregnancies with a previous partner(s)?  yes (go to 3.1)    no (if no go to 3.7)

- 3.1 # Previous pregnancies \_\_\_\_\_
- 3.2 # Live infants \_\_\_\_\_
- 3.3 # Spontaneous abortions (miscarriages) \_\_\_\_\_
- 3.4 # Fetal deaths (stillbirths) \_\_\_\_\_
- 3.5 # Elective abortions \_\_\_\_\_
- 3.6 # Outcomes with defects \_\_\_\_\_ (specify defects) \_\_\_\_\_
- 3.7 Paternal family history of birth defects – Describe any history of birth defects

**CONFIDENTIAL**

**Ribavirin Pregnancy Registry**  
**Male Sexual Partner Exposure/Family History**

Registry ID \_\_\_\_\_ (OFFICE USE ONLY)

**HEALTH CARE PROVIDER INFORMATION)**

Name \_\_\_\_\_

Specialty \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

\_\_\_\_\_

Fax \_\_\_\_\_

\_\_\_\_\_

Email \_\_\_\_\_

Alternate Contact \_\_\_\_\_

Provider's Signature \_\_\_\_\_

Date \_\_\_\_\_

dd mon yyyy