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 1-11
   - Total Dose: Provide the total dose and interval (day, wk) with units (e.g., ribavirin 40 mg/week).
   - 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
   2.1 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)?
   2.2 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.

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/.
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)
      2. COPEGUS® (ribavirin)
      3. REBETRON® (Rebetol + Intron A)
      4. ribavirin (trade name unknown)
      5. peginterferon alpha (generally given 1 time per week)
      6. interferon alpha (generally given 3-7 times per week)
      7. interferon (type of interferon unknown)
      8. RIBASPHERE™ (ribavirin)
      9. Ribavirin (Sandoz)
     10. Ribavirin (Teva)
     11. Ribavirin (Zydus)

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

<table>
<thead>
<tr>
<th>Med. Code</th>
<th>Total Dose</th>
<th>Route</th>
<th>Date</th>
<th>Treatment Course Began</th>
<th>Date Treatment Course Stopped</th>
<th>Ongoing</th>
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</thead>
<tbody>
<tr>
<td>1-11</td>
<td>*please indicate (mg/day or wk or mg/kg/day)</td>
<td>(enter code)</td>
<td>(ddmonyyyy)</td>
<td>(ddmonyyyy)</td>
<td>(ddmonyyyy)</td>
<td>(if ribavirin therapy continuing)</td>
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   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)
   2.2 How often does the male sexual partner have unprotected sexual intercourse with the pregnant female?
      - Multiple times a week
      - Once a week
      - Once every 2 weeks
      - Once a month
      - Not at all
      - 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 ________________________________

Ribavirin Pregnancy Registry
Research Park; 1011 Ashes Drive; Wilmington, NC 28405
Phone: 800-593-2214, Fax: 800-800-1052
Version (Nov 2005)

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<th><strong>HEALTH CARE PROVIDER INFORMATION</strong></th>
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<td>Name</td>
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Registry ID ________________ (OFFICE USE ONLY)