❋ ANNOUNCEMENT ❋
RIBAVIRIN PREGNANCY REGISTRY

Ribavirin Pregnancy Registry

The Ribavirin Pregnancy Registry (Registry) is a program to monitor pregnancy exposures to ribavirin. The development of the Registry was mandated by FDA. The Registry was implemented in January 2004.

What is the Registry?

The Ribavirin Pregnancy Registry is a voluntary, largely prospective registry designed to collect observational data on pregnancies and the outcomes following a pregnancy exposure to ribavirin. The Registry also collects "retrospective" information, i.e., reports after the outcome of the pregnancy is known for additional analysis. Ribavirin exposures may be direct, through the pregnant female or indirect, through her male sexual partner.

Why is the Registry important?

Ribavirin, a nucleoside analog, is indicated in combination with alpha interferon or pegylated alpha interferon for the treatment of chronic hepatitis C (HCV).The incidence of HCV is highest in the population with reproductive potential (25 – 45 years of age) (CDC, 2001). Therefore, it is possible that pregnancy exposures may occur during or following HCV treatment with ribavirin. In addition, it has been shown that significant teratogenic and/or embryocidal effects occurred in all animal species exposed to ribavirin. There are no data to determine if this is also the case in humans. However, ribavirin has been given an FDA Pregnancy Category X, indicating it should not be used in women who are pregnant (and for ribavirin specifically, for 6 months after treatment is stopped or in men whose sexual partners may become pregnant during or for 6 months after treatment is stopped).

This Registry is the only program expressly established to evaluate prenatal exposures to ribavirin. It is not possible to study exposures in pregnancy any other way. Registry data supplement other sources of data and as data accrue, may assist clinicians and patients in weighing risks of ribavirin exposure in pregnancy. The lack of data on ribavirin pregnancy exposures and their outcomes makes such a Registry an essential component of the ongoing risk management program and epidemiologic studies on the safety of this product.

How to participate in the Registry

The Registry will accept reports of pregnancy exposures to ribavirin from health care providers, pregnant patients, or pregnant patient's male sexual partners. The data collected are minimal and targeted. Data are collected at each trimester and at outcome of pregnancy through the obstetric health care provider and for a live birth for 12 months after birth through the pediatric health care provider. Patient identity is kept confidential. The Registry assigns ID numbers to follow the pregnant female until a signed authorization for release of medical information is obtained.

How are data collected by the Registry and analyzed and reported?

An important aspect of the Registry is the Scientific Advisory Board formed to oversee the Registry data and analysis and presentation of results. The Board is composed of specialists in obstetrics and gynecology, infectious diseases/hepatology, and epidemiology, with *ex-officio* members from the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).

The data are collected through the Registry Coordinating Center (see contact information below). A Registry Interim Report, published annually, summarizes the aggregate data.

Why should I participate?

This Registry is the primary source for collecting and evaluating direct or indirect exposures to ribavirin in pregnancy. Your contribution to this collaborative program enables you and your colleagues to assist in this public health initiative.

The success of the Registry relies on participation of patients and health care providers who report ribavirin pregnancy exposures and assist in obtaining pregnancy information through outcome and postnatal information on live birth outcomes.

How can I get more information?

Write, call, fax, or email at:

The Ribavirin Pregnancy Registry
1011 Ashes Drive; Wilmington, North Carolina 28405
US, Canada (800) 593-2214 (Toll-free phone) (800) 800-1052 (Toll-free fax)
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