

## About the Registry

- Initiated following IRB approval in December 2003 as part of the manufacturers' FDA postmarketing commitment for safety surveillance of ribavirin.

- Conducted through a Call Center.



- Patient enrollment is easy and can be completed over the phone, by the exposed patient or a health care provider who may report anonymously.

- Registry staff obtain verbal informed consent during their telephone interactions with the patient.

## About Ribavirin

Ribavirin, a nucleoside analog, is approved for use in combination with alpha interferon or pegylated alpha interferon for treatment of chronic hepatitis C infection.

- Ribavirin showed significant teratogenic and/or embryocidal effects in all animal species exposed to ribavirin. However, there is little study data in humans.

- Ribavirin is co-administered with interferon which is known to be an abortifacient.

- Ribavirin has been assigned an FDA Pregnancy Category X, with a black box warning:

*“Contraindicated in pregnancy. Studies in animals or humans, or investigational or post-marketing reports, have shown fetal risk which clearly outweighs any possible benefit to patient.”*

*The success of the Registry relies on your participation. Patients and health care providers who report ribavirin pregnancy exposure outcomes contribute to much needed prescribing information.*

*Despite the FDA Category X designation, warning against pregnancy, pregnancy exposures to ribavirin continue to occur.*

## For more information

[www.RibavirinPregnancyRegistry.com](http://www.RibavirinPregnancyRegistry.com)

The Ribavirin Pregnancy Registry  
1011 Ashes Drive  
Wilmington, NC 28405

800-593-2214 (toll free phone)  
800-800-1052 (toll free fax)

[pregnancyregistries@incresearch.com](mailto:pregnancyregistries@incresearch.com) (email)

*For information on a specific ribavirin product contact the manufacturer.*

May 2016

# RIBAVIRIN PREGNANCY REGISTRY



## Ribavirin Registry Products

**COPEGUS®**

**REBETOL®**

**RIBASPHERE®**

Four generic ribavirin products  
(without a brand names)

## What is the Registry?

The Ribavirin Pregnancy Registry collects observational data on pregnancy exposures to ribavirin. Eligible women are enrolled before the outcome of pregnancy is known, though information on any pregnancy exposures is accepted. Ribavirin exposures may be through the pregnant female or through her male sexual partner.



## Why is the Registry important?

This Registry is the only program expressly established to evaluate prenatal exposures to ribavirin as it is not reasonable to study exposures in pregnancy in any other way. Registry data supplement other sources of data about ribavirin. As data accrue, more information will become available to assist clinicians and patients in weighing risks of ribavirin exposure in pregnancy.

Ribavirin, in combination with alpha interferon or pegylated alpha interferon, is indicated for the treatment of chronic hepatitis C infection.

However, even though ribavirin use is contraindicated in pregnancy, pregnancy exposures do occur.

Ribavirin has been shown to have significant teratogenic and/or embryocidal effects in all animal species exposed to ribavirin. Because there is little study data in humans, this Registry will assist in determining whether these effects occur in humans.

FDA has assigned ribavirin a Pregnancy Category X, indicating ribavirin should not be used in women who are pregnant (and for 6 months after treatment is stopped or in men whose sexual partners may become pregnant during or for 6 months after his treatment is stopped).

## How can I participate in the Registry?

The Registry accepts reports of pregnancy exposures to ribavirin from health care providers, pregnant patients, or pregnant patients' male sexual partners. The data collected are minimal and targeted. Data are collected at each trimester and at outcome of pregnancy through the health care provider. Live-born infants are followed for 12 months following birth through the pediatric health care provider.

Patient identity is kept confidential. The Registry assigns ID numbers to follow the pregnant women until a authorization for release of medical information is obtained. Verbal consent is obtained for telephone reported patient exposures.

## Will participation benefit me and my patients?

This Registry is the primary source for collecting and evaluating direct (through the pregnant woman) or indirect (through her male sexual partner) exposures to ribavirin in pregnancy. Your contribution to this collaborative program enables you and your colleagues to assist in this public health initiative.

## How are the data analyzed and reported?

An important aspect of the Registry is the Scientific Advisory Board formed to oversee the Registry data analysis and presentation of results. The Board is composed of specialists in maternal-fetal medicine, infectious diseases/hepatology, and epidemiology, with member(s) from the Centers for Disease Control and Prevention (CDC).

The Board meets annually to evaluate the Registry data and provide a consensus statement for the Registry Interim Report, which summarizes the aggregate data.

