Ribavirin Pregnancy Registry

Female Patient Information Sheet

RIBAVIRIN PREGNANCY REGISTRY Coordinating Center Research Park, 1011 Ashes Drive, Wilmington, NC 28405 800-593-2214 (toll-free telephone) 800-800-1052 (toll-free fax)

Ribavirin (brand names: COPEGUS®, REBETOL®, REBETRON®, RIBASPHERE®, and generic ribavirin products without brand names) is a drug used to treat hepatitis C (HCV). There are studies in animals that show that animals given ribavirin while they were pregnant had offspring with birth defects. However, there is not good information about what happens to babies of women who are exposed to ribavirin during their pregnancy or who become pregnant within 6 months after ribavirin is stopped. The Ribavirin Pregnancy Registry was begun to learn more about what happens to babies exposed to ribavirin through their mothers. A federal agency, the Food and Drug Administration (FDA), has required that the drug companies (Hoffmann-La Roche, Schering Plough and generic manufacturers) who manufacture ribavirin run this Registry.

Your baby has been exposed to the drug, ribavirin during this pregnancy, if you or your male sexual partner has taken the drug while you were pregnant or if you became pregnant within 6 months after the drug was stopped. This Registry is asking permission from you to be part of this Registry, which collects information on pregnant women such as you.

What do I have to do to participate?

All you need to do is give us your permission: (1) for us to contact your doctor(s) and your baby's doctor(s), and (2) for your doctor(s) and your baby's doctor(s) to disclose information about you, your pregnancy, and your baby to us. With your permission, we will collect information from the doctor(s) you are seeing for this pregnancy while you are pregnant. Then, after you have your baby, we will contact your baby's doctor(s). You can give the Registry these permissions by completing the portion of the form that asks you to identify your doctor(s) and your baby's doctor(s). If the Registry has your permission, this Registry will collect information from your doctor(s) on your exposure to ribavirin and how you and your baby are doing during your pregnancy.

After your baby is born, the Registry will ask for information on your baby 1) at the time of birth, 2) when your baby is 6 months old, and 3) when your baby is 12 months old.

To be part of this Registry you will not have to make any extra office visits, take any extra tests, or take any additional drugs. If your doctor(s) does not answer our calls, we may ask you for some of this information directly.

What kind of information will be given to the Registry?

To learn more about the effects of ribavirin to babies born after being exposed to ribavirin during pregnancy, the Registry needs some information about you, about ribavirin and other drugs you are taking during pregnancy and about other medical conditions during pregnancy. When your baby is born the Registry will ask for information about your baby and his health until your baby is one year old. This information will be put on Registry forms which are used by the Registry.

You can see these forms on www.ribavirinpregnancyregistry.com. Your doctor will also be asked to supply any relevant portion of your baby's medical record. The medical record may identify you by name, address, medical record number, Social Security number, health plan number, or other identifier. If you or your baby has any serious adverse events during the follow-up, that information will be given to the Registry if your doctor(s) or your baby's doctor(s) learn about it.

How will the Registry keep my information confidential?

Once medical information that identifies you or your baby is disclosed by a doctor to the Registry, the information is no longer protected by federal medical privacy regulations and could be subject to re-disclosure. It is the policy of the Registry, however, not to disclose to anyone outside of the Registry any information that identifies you by name, unless there is a problem that must be reported to the manufacturer of ribavirin to send to the FDA or unless otherwise required by law. Results of this Registry may be published, but will never identify you by name. Your medical records will remain confidential to the extent allowed by law.

How long does my permission last?

Your permission for your doctor(s) and your baby's doctor(s) to disclose information to the Registry will expire once the Registry has ended.

What if I decide not to participate?

Participation is totally voluntary. If you decide not to participate, it will not affect your treatment for Hepatitis C or your pregnancy or your baby's treatment. Further, if you do participate and decide later that you want to stop allowing information to be given to the Registry, you may do so at any time by sending a letter to the Registry at the address at the top of this form. Your decision to withdraw from participation cannot reverse any disclosure of information that has already been made to the Registry. Your decision to withdraw from participation will not affect yours or your baby's treatment.

Will I be compensated for participating in the Registry?

No. Agreeing to provide information to the Registry offers you no direct benefit. However, the information learned from this Registry may help other women exposed to ribavirin during their pregnancies.

Voluntary Permission

I have read the above description of the Registry called the Ribavirin Pregnancy Registry. I understand that if I have questions or wish further information about the Registry I may contact the Registry at the telephone number (free long distance call) at 800-593-2214 or at the address at the top of this form.

If you have questions about your rights as a research subject, you may contact: Western Institutional Review Board (WIRB) 3535 Seventh Avenue, SW Olympia, Washington 98502 Telephone: 1-800-562-4789

WIRB is a group of people who perform independent review of research.