



HCSP FACT SHEET

• HCV TREATMENT: GENERAL INFORMATION •

Pregnancy Drug Categories

Written by: Alan Franciscus, Editor-in-Chief

Foreword

Which drugs are safe to take for a woman while she is pregnant? If a woman becomes pregnant while on therapy is there a risk to the fetus? If a woman is pregnant, which drugs increase the risk of birth defects? To help guide medical providers and patients, the Food and Drug Administration (FDA) has established certain categories that for the most part define what is safe and what is not safe. But there are gray areas within most of the categories. This is why it is so important to seek medical advice—medical providers base decisions on a variety of factors, such as does the risk outweigh the benefit, personal experience using a certain drug and the latest medical research.

The pregnancy categories are only applied to medications that have been approved by the FDA. Over-the-counter medications (OTC), herbs and most supplements are not assigned a pregnancy classification unless they have been previously scrutinized by the FDA. In these instances medical providers will use their previous experience or information from scientific sources to advise what is safe or unsafe to take.

In a perfect world every drug would have solid scientific data on humans to advise about the potential risk of medications, but this isn't always the case. There are many reasons why studying a drug in humans isn't feasible or why pharmaceutical companies don't pursue these trials, such as the obvious risk of exposing pregnant women and their unborn babies to certain drugs, the cost of studying the issues and the potential lawsuits the pharmaceutical companies may be subject to. As a result much of the information about medications and pregnancy is based on test tube or animal studies and anecdotal information about drugs that have a long history of use.

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**EXECUTIVE DIRECTOR,
EDITOR-IN-CHIEF,
HCSP PUBLICATIONS**
Alan Franciscus

DESIGN
*Leslie Hoex,
Blue Kangaroo Design*

PRODUCTION
C.D. Mazoff, PhD

CONTACT INFORMATION

Hepatitis C Support Project
PO Box 15144
Sacramento, CA 95813
alanfranciscus@hcvadvocate.org

The information in this fact sheet is designed to help you understand and manage HCV and is not intended as medical advice. All persons with HCV should consult a medical practitioner for diagnosis and treatment of HCV.

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Pregnancy Drug Categories

*Pregnancy Categories**

Category A:

In human studies, pregnant women used the medicine and their babies did not have any problems related to using the medicine.

Category B:

In humans, there are well-controlled studies. But in animal studies, pregnant animals received the medicine, and the babies did not show any problems related to the medicine.

OR

In animal studies, pregnant animals received the medicine, and some babies had problems. But in human studies, pregnant women used the medicine and their babies did not have any problems related to using the medicine.

Category C:

In humans, there are no well-controlled studies. In animals, pregnant animals treated with the medicine

had some babies with problems. However, sometimes the medicine may help the human mothers and babies more than it might harm them.

OR

No animal studies have been done, and there are no good studies in pregnant women.

Category D:

Studies in humans and other reports show that when pregnant women use the medicine, some babies are born with problems related to the medicine. However, in some serious situations, the medicine may still help the mother and the baby more than it might harm them.

Category X:

Studies or reports in humans or animals show that mothers using the medicine during pregnancy carry a very high risk to the proper development of the fetus. ***These medicines should never be used by pregnant women.***

*Source: Food and Drug Administration

FDA Approved Medications for Treating HCV.

Drug	Category	Indication
Incivek (Telaprevir)	B	HCV
Interferon (Intron A)	C	HCV
Ledipasvir (Harvoni - ledipasvir+sofosbuvir)	B	HCV
Pegylated interferon alfa-2a (Pegasys)	C	HCV
Pegylated interferon alfa-2b (PegIntron)	C	HCV
Sofosbuvir (Sovaldi, Harvoni (sofosbuvir/ledipasvir))	B	HCV
Simeprevir (Olysio)	C	HCV
Ribavirin (Rebetol, Copegus, etc.)	X	HCV
Victrelis (Boceprevir)	B	HCV
Viekira Pak (Ombitasvir, Paritaprevir, Ritonavir, Dasabuvir)	B	HCV

Pregnancy Drug Categories

Ribavirin warning: Ribavirin has been shown to cause birth defects and miscarriages. Women of childbearing age, their male partners, and female partners of male patients taking ribavirin **must use at least two forms of effective contraception** during treatment and during the six-month post-treatment follow-up period.

There is a ribavirin pregnancy registry that is tracking outcomes of exposures to ribavirin during pregnancy:
www.ribavirinpregnancyregistry.com

Related publications:

- **Easy C: Genotype 1 Treatment: Harvoni (Sofosbuvir & Ledipasvir)**
http://hcvadvocate.org/hepatitis/easyfacts/Harvoni_e.pdf
- **Easy C: Genotype 1 Treatment: Viekira Pak**
http://www.hcvadvocate.org/hepatitis/easyfacts/Viekira_e.pdf
- **Patient Assistance Programs**
http://hcvadvocate.org/hepatitis/factsheets_pdf/Patient_Assistance.pdf

For more information

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| <ul style="list-style-type: none"> • American Association for the Study of Liver Diseases
 www.aasld.org • Centers for Disease Control and Prevention
 www.cdc.gov | <ul style="list-style-type: none"> • Food and Drug Administration (FDA):
 www.fda.gov • Mayo Clinic
 www.mayoclinic.com |
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Visit our websites to learn more about viral hepatitis:

www.hcvadvocate.org • www.hbvadvocate.org
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