

Hepatitis B Fact Sheet

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a series of fact sheets written by experts in the field of liver disease

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Pregnancy Drug Categories

Which drugs are safe to take while a woman 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 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 in the real world. 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 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.

*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 no good 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.



Pregnancy Drug Categories

Category C:

In humans, there are no good 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 preg-

nancy may have babies with problems related to the medicine. There are no situations where the medicine can help the mother or baby enough to make the risk of problems worth it. These medicines should never be used by pregnant women.

***Source:** Food and Drug Administration

See also: Management of hepatitis B in pregnancy: Weighing the options *Cleveland Clinic Journal of Medicine* May 2009 vol. 76 Suppl 3 S25-S29 www.ccjm.org/content/76/Suppl_3/S25.full

FDA Approved Medications for Treating HBV.

Drug	Category	Indication
Tenofovir (Viread)	B	HBV and HIV
Telbivudine (Tyzeka)	B	HBV
Interferon (Intron A)	C	HCV and HBV
Pegylated interferon alfa-2a (Pegasys)	C	HCV and HBV
Pegylated interferon alfa-2b (PegIntron)	C	HCV
Entecavir (Baraclude)	C	HBV
Adefovir (Hepsera)	C	HBV
Lamivudine (Epivir-HB)	C	HBV and HIV

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

For more information about hepatitis B, visit the following websites.
Hepatitis B Foundation: www.hepb.org • HIVandHepatitis.com

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