testing and treatment

Hepatitis C information resources

American Liver Foundation
75 Maiden Lane, Suite 603
New York, NY 10038
(800) GO-LIVER (465-4837)
(888) 4-HEP-ABC (443-7222)
http://www.liverfoundation.org

Centers for Disease Control and Prevention (CDC)
1600 Clifton Road
Atlanta, GA 30333
(888) 4-HEP-CDC (443-7232)
http://www.cdc.gov/hepatitis

Hepatitis Foundation International
504 Blick Drive
Silver Spring, MD 20904-2901
(800) 891-0707
(301) 622-4200
http://www.hepfi.org

Hep C Connection
1177 Grant Street, Suite 200
Denver, CO 80203
(800) 522-HEPC (4372)
(303) 860-0800
http://www.hepc-connection.org

National AIDS Treatment Advocacy Project (NATAP)
580 Broadway, Suite 1010
New York, NY 10012
(888) 26-NATAP (62827)
(212) 219-0106
http://www.natap.org

National Hepatitis C Coalition, Inc.
P.O. Box 5058
Hemet, CA 92544
National Hepline: (909) 658-4414
http://www.nationalhepatitis-c.org

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Roche Pharmaceuticals

Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199
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Hepatitis C: From testing to treatment

Hepatitis C is a disease caused by a virus that primarily attacks the liver. Hepatitis C can cause serious health problems—even in patients who have no symptoms at all. So, if you have been exposed to any of the risk factors listed on the next page, you should talk with your doctor about being tested. The only way to find out for sure if you have hepatitis C is through special tests your doctor can do. If you find out you do have hepatitis C, your doctor will talk with you about your treatment options.

This booklet will explain several tests for hepatitis C, as well as treatment options. We hope it provides you with a good overview, but, remember, your doctor or nurse is your best source for information about your medical condition and its treatment.

NOTE: Since you may not know all of the medical words in this booklet, we've included a glossary with definitions at the back.

Who should be tested for hepatitis C?

Hepatitis C is caused by a blood-borne virus. This means you can get hepatitis C by coming in contact with infected blood. It is also possible to contract hepatitis C from infected body fluids, although transmission through body fluids is less likely. Some of the ways it can happen are

- Blood transfusions (before July 1992), operations and infected blood products
- Intravenous drug use (past or present—even one-time use)
- Tattooing and body piercing
- Occupational, eg, needlestick and dental treatment
- Needles, dialysis equipment and other medical equipment
- Transmission from mother to child during birth
- Shared personal hygiene items (such as razors, toothbrushes, nail files)
- Intramucosally (that is, through the tissues lining body openings since blood can be present), when taking cocaine or other drugs
- Sexual activity that involves contact with infected blood or body fluids
- Acupuncture

Remember, the sooner you know if you have hepatitis C, the sooner you and your doctor can take steps to fight back.

Please see the glossary at the end of this booklet for definitions of key words.

How can I find out if I have hepatitis C?

There are many types of blood tests that can show whether or not you have hepatitis C. A few of them are discussed below.

Antibody detection tests

An antibody is a protein made by the body to get rid of something harmful, such as a virus. Antibodies are like specially trained soldiers inside your body. There are specific antibodies for each virus waiting to fight different types of viral infections. When someone has hepatitis C, the body sends out the right antibodies to fight back against that disease. **Therefore, hepatitis C antibody detection tests look for hepatitis C antibodies in the blood.** If they're found, it usually means that you have or have had hepatitis C, since antibody tests cannot determine if the virus is currently active.

ELISA (Enzyme Linked Immunosorbent Assay) and **RIBA*** (Recombinant Immunoblot Assay) are two types of antibody detection tests. Both the ELISA and RIBA tests work well, but the ELISA is more commonly used as the initial hepatitis C test.

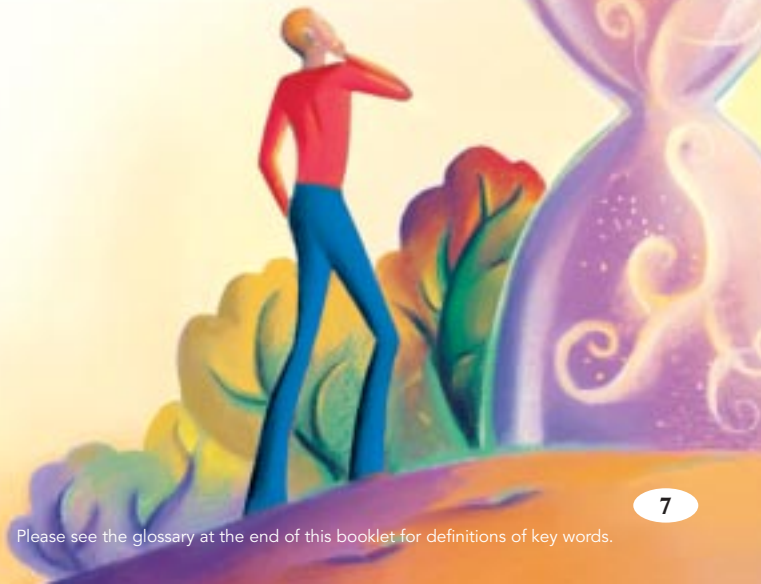
Virus detection tests

These tests look for the presence of the hepatitis C virus in the blood. If the virus is detected, it means you have hepatitis C.

One thing doctors look for when comparing virus detection tests is sensitivity (how well the test finds the hepatitis C virus in your body). The greater the sensitivity of a test, the more capable it will be at finding low levels of hepatitis C virus in your body.

The most sensitive virus detection test is called a PCR (Polymerase Chain Reaction) test. While there are several PCR tests available through local laboratories, the AMPLICOR® HCV test is the name of the first PCR test approved by the US Food and Drug Administration (FDA) for the detection of hepatitis C. Other non-approved HCV detection tests may be used as well, especially in clinical trials.

*RIBA is a registered trademark of Chiron Corp.



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Genotype tests

If you have the hepatitis C virus in your body, your doctor may also want to see what type of hepatitis C virus you have. **Genotype tests are virus detection tests, but with the added ability to determine the type of hepatitis C virus that's present in your blood**. Why does the type matter? Well, sometimes knowing the specific type of hepatitis C virus a person has can help doctors determine the chances for treatment success.

Liver function tests

Liver function tests (LFTs) are the most commonly used way to check for liver problems. **These tests look for chemicals in your body that are produced when the liver does its various jobs**.

An example of an LFT is the alanine amino-transferase (ALT) test. An increase in ALT in the blood above normal range can mean ongoing liver damage. While ALT tests can identify liver damage, that damage may or may not be the result of hepatitis C. In some patients with hepatitis C, ALT levels remain normal. It's important to note that **ALT tests should be done often and over time** to get the best indication of the level of liver damage.

To find out how healthy your liver is, your doctor may also want to do a biopsy. A liver biopsy is when a tiny sample of the liver is removed (through a needle) and examined in a laboratory. **A liver biopsy is the best way to determine the health of your liver.**

Determining liver health is important not only for diagnosing hepatitis C but also for finding out a patient's risk of developing more serious liver problems.

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How can I fight hepatitis C?

According to the latest medical research, **combination therapy (taking both interferon and ribavirin) is the gold standard for treating hepatitis C.** But more on that in a moment.

Interferon is no stranger to the human body. In fact, your body is constantly making interferon, and makes even more when it tries to fight off an intruder, such as a virus. You've experienced this if you've ever had the flu. When you have the flu, your body makes extra interferon to defeat the virus that's causing the illness. It's this extra interferon that also causes symptoms like fever, nausea and fatigue.

To get enough interferon, some people with hepatitis C need to inject interferon into their bodies. While the **interferon** that's used for injection is slightly different from the kind your body makes, **it helps the body defeat the virus in two ways:**

- First, interferon attaches to healthy cells and helps them defend themselves against viruses
- Second, the medication helps focus the activity of the immune system on the invading virus to stop the virus from multiplying

Interferon is also thought to help the body get rid of infected cells while preventing healthy cells from being infected.

In addition, making lifestyle changes along with taking your treatment may be the best approach for you. However, this should be done under a doctor's supervision.

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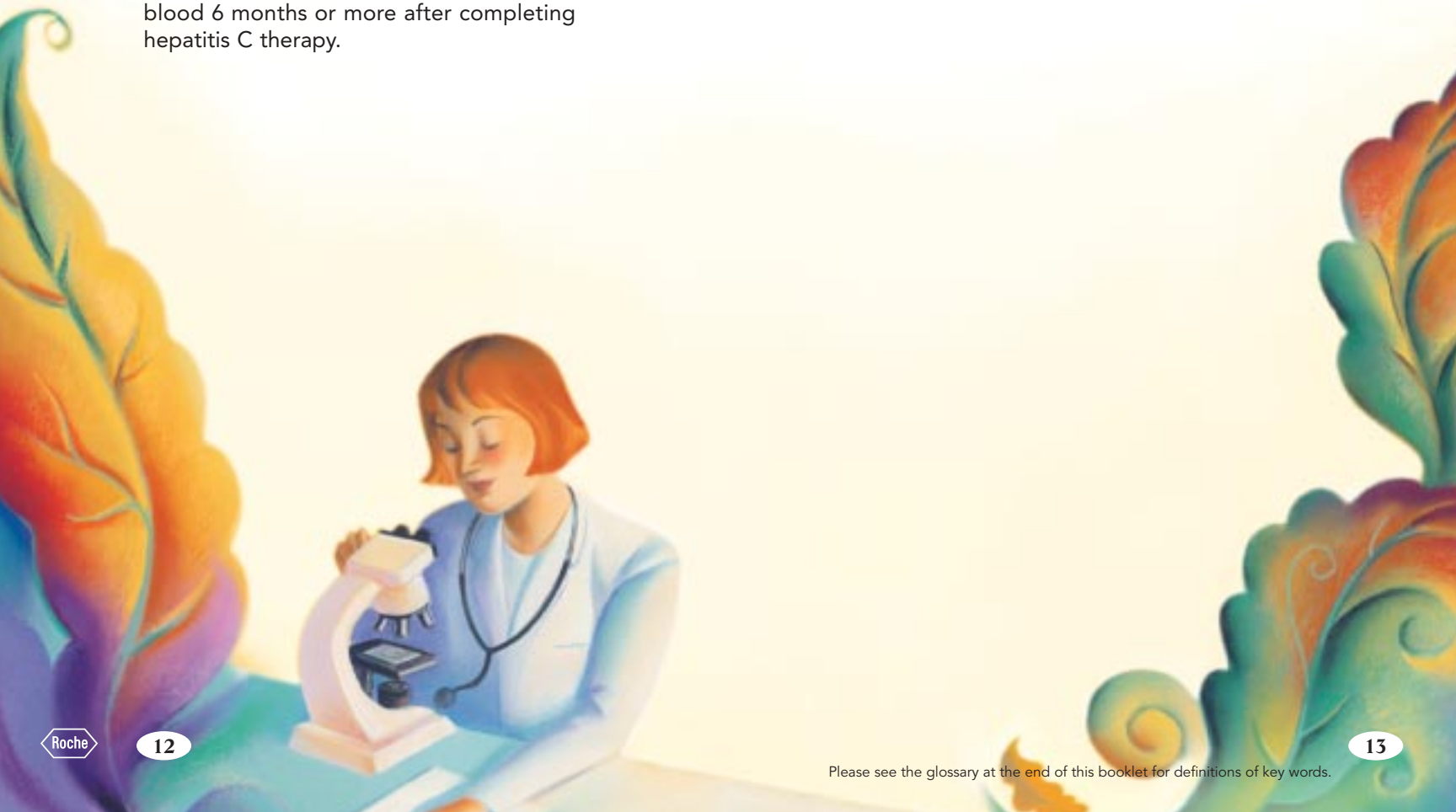
How do I know if interferon is working?

To find out if interferon is working, doctors look at what's called "**virologic response**" and "**histologic response**."

Virologic response is the more common way of looking at hepatitis C treatment success. To measure virologic response, doctors use a blood test to measure how much hepatitis C virus is in the blood. The best virologic response would be a "sustained virologic response," which simply means that the virus can't be seen in your blood 6 months or more after completing hepatitis C therapy.

Another way to evaluate hepatitis C therapy is to look at **histologic response** to see if liver inflammation and fibrosis (scarring) have improved.



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Interferon: What are my options?

Once you find out you have hepatitis C, your doctor will help you decide if treatment is right for you. If your doctor decides you should be treated, there are basically 3 types of interferon therapy to choose from:

1. Alpha interferon
2. Pegylated alpha interferon (newest form of interferon therapy)
3. Combination therapy—taking ribavirin along with certain alpha interferons

Since stomach enzymes would destroy interferon if it were taken by mouth, interferon needs to be injected. And in the case of alpha interferon, you would need to inject 3 times per week. However, pegylated alpha interferon—which uses an advanced technology—needs to be injected only once a week. Pegylation will be discussed in more detail later in this booklet.

The usual length of treatment for hepatitis C is 24 to 48 weeks (exact length of therapy will be determined by your doctor). However, treatment is often stopped if a person taking alpha-interferon or alpha-interferon-based therapy doesn't have a virologic response at some point during the first 3 to 6 months of treatment.

Ribavirin: How does it help interferon do its job?

Ribavirin is a medication that is often used with certain alpha interferons to stop the hepatitis C virus from multiplying. Although ribavirin cannot fight hepatitis C on its own, studies have shown that it does help alpha interferon work better. Ribavirin is a pill; so although you won't need to inject it, you'll need to take several pills every day in addition to your alpha-interferon therapy.

Since all medications can cause side effects, it's possible that you could experience side effects while taking ribavirin and/or alpha interferon. Your doctor can talk more about any concerns you may have.

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Things you should know

Like all medications, alpha interferons and ribavirin can cause side effects—some of which may be severe. Alpha interferons have been known to cause new or worsening mental health problems such as depression or suicidal behavior (including thoughts about suicide and suicidal attempts); trouble breathing, chest pain, change in your vision, unusual bleeding or bruising, high fever or worsening of psoriasis. Other side effects associated with alpha interferons include headache, fatigue, fever, nausea, muscle pain, and sleeplessness. These disorders generally resolve after stopping therapy.

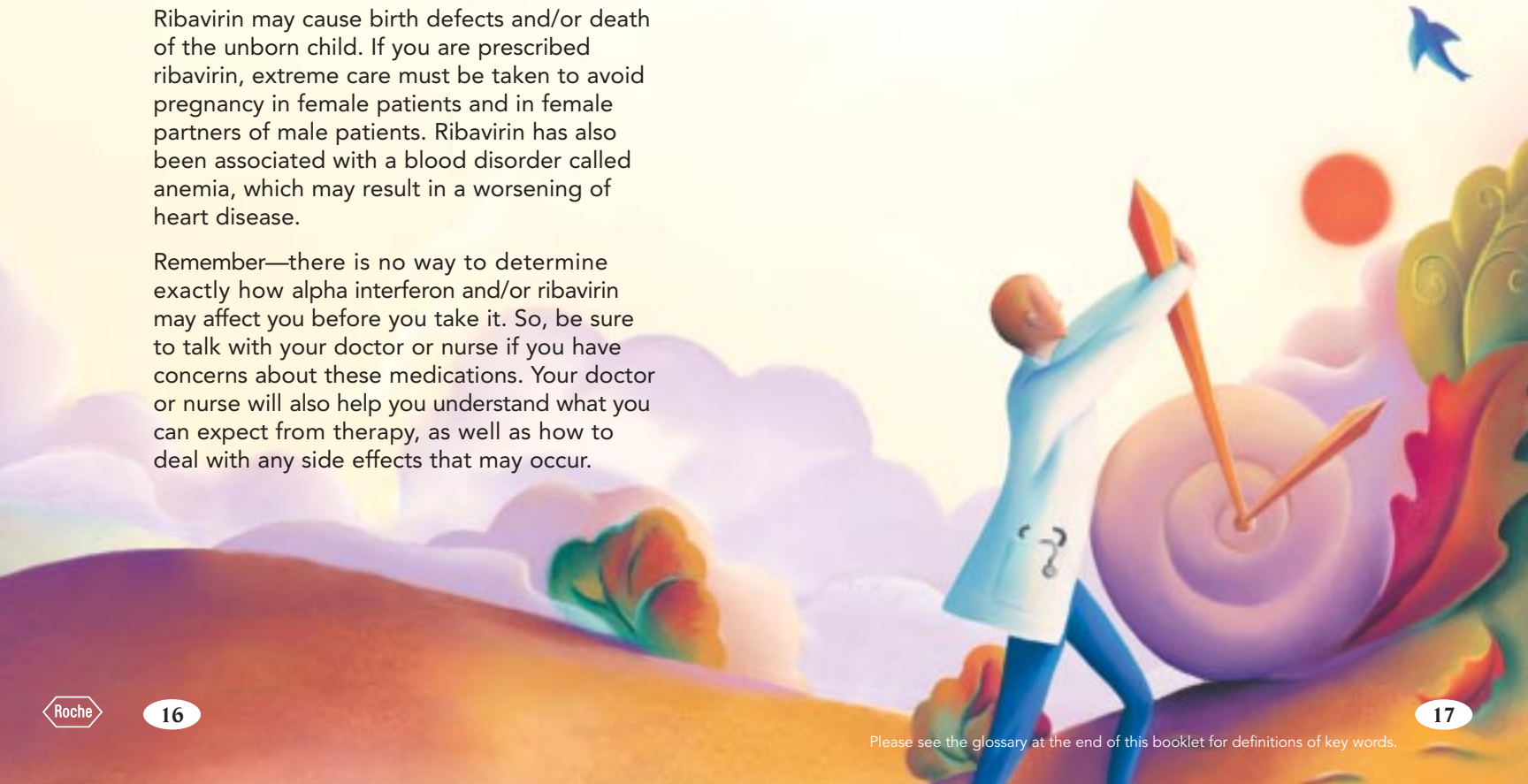
Ribavirin may cause birth defects and/or death of the unborn child. If you are prescribed ribavirin, extreme care must be taken to avoid pregnancy in female patients and in female partners of male patients. Ribavirin has also been associated with a blood disorder called anemia, which may result in a worsening of heart disease.

Remember—there is no way to determine exactly how alpha interferon and/or ribavirin may affect you before you take it. So, be sure to talk with your doctor or nurse if you have concerns about these medications. Your doctor or nurse will also help you understand what you can expect from therapy, as well as how to deal with any side effects that may occur.

Pegylation: Helping to keep interferon around longer

"Pegylation" is a technology used to alter the way some proteins work in hopes of improving their performance. To do this, one or more chains of polyethylene glycol (also known as PEG) are attached to a protein molecule (such as interferon). Once attached, the PEG helps provide a protective barrier around the protein molecule.

This barrier may help provide many benefits over molecules that do not have a PEG. For example, pegylated interferons tend to be dosed once per week.



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Where do I go from here?

As you can see, there's a lot to know about hepatitis C tests and therapies. Your doctor can help you make sense of all of your options. If you think you may have hepatitis C, and haven't been tested yet, it's especially important to see your doctor.

Glossary

Antibody: A protein released by the body to fight against an intruder (eg, a virus)

Blood-borne virus: A virus that circulates in the blood and can be transmitted from one person to another during blood-to-blood contact (eg, through shared needles)

Histology [hist-AH-luh-jee]: The study of tissue under a microscope

Interferon [in-ter-FEER-ahn]: A protein that fights an intruder, such as a virus, by stopping it from reproducing

Liver biopsy [BYE-op-see]: A tiny sample of the liver removed (with a needle) and examined in a laboratory

Pegylation [peg-uh-LAY-shun]: A process that helps interferon remain in the body longer

Ribavirin [RYE-buh-vye-rin]: A medication, often prescribed with certain alpha interferons, to make the alpha interferon more effective against the hepatitis C virus

Sustained virologic response: The virus remains at undetectable levels in the blood for 6 or more months after the end of treatment