

**THINKING
ABOUT
TREATMENT
FOR
HEPATITIS C?**



→ **IF YOU** have hepatitis C and are thinking about using clinical treatment, this booklet contains information about:

- what treatments are available
- the possible side effects of treatments
- the effectiveness of treatments
- eligibility for government-subsidised treatment
- where to get more information and support.

A list of questions to ask your doctor or specialist before starting treatment, and a glossary of terms is also included.

Discuss the information in this booklet with your doctor. For more information about hepatitis C treatments, see the 'further reading' and contacts listed at the back of this booklet.

This booklet is designed to provide information to help people with hepatitis C make an informed decision about whether they should consider using treatment.

Note: The information and advice provided in this booklet is not intended to replace professional medical advice. Consultation should be made with medical professionals before acting on any information on treatments for hepatitis C provided in this resource.



DECIDING ABOUT TREATMENT

WHEN When you were first diagnosed with hepatitis C, you may have felt angry, confused, depressed - or nothing at all.

Often the time of diagnosis is not the best time to be making decisions about treatment. Hepatitis C is a viral illness that progresses slowly, so most people can take time to consider their treatment options.

Treatment for hepatitis C lasts for either 24 or 48 weeks, so it is important to be well informed about hepatitis C and the available treatments before you begin.

Deciding to start treatment is a personal decision. Talking with your doctor may help you decide. You will also need to have a series of tests before you begin treatment. These tests generally include:

- a liver function test – blood test to measure the levels of enzymes in your blood stream
- a liver biopsy – day surgery to determine the extent of liver injury
- a polymerase chain reaction test or PCR (blood test) to detect the presence and quantity of hepatitis C in the blood and determine the strain of virus (or genotype).

Deciding you want to start treatment does not automatically mean that you will be accepted for treatment, and it is important to discuss with your doctor what treatment options are available to you.

The decision to be treated can depend on your individual situation and include issues like family and work commitments, relationships, the level of support you have and lifestyle practices.

Before treatment, it's a good idea to find out more about your options. You can get free information and support from:

- Hepatitis Councils and/or support groups in all capital cities and some regional areas of Australia
- haemophilia organisations for people with bleeding disorders
- peer-based injecting drug user groups, and
- a range of community-based organisations or government agencies.

See Contacts on page 24.

WHAT TREATMENTS ARE AVAILABLE?

THE current pharmaceutical (or conventional) treatment for hepatitis C is combination therapy involving the use of pegylated interferon and ribavirin.

While this is the standard treatment, a small number of people cannot take ribavirin. In these cases, monotherapy with pegylated interferon alone is available. Monotherapy is not as effective in clearing the hepatitis C virus as combination therapy.

Other therapies include complementary and alternative therapies, such as Traditional Chinese Medicine (page 13). These are most often used to boost the body's general health and support the liver, rather than clear the virus.

Combination therapy is the preferred form of treatment for clearing the virus, but individual treatment options vary and you should check with your doctor or specialist about which form of treatment is best for you.

Conventional treatments

Conventional treatment is the use of mainstream medical services and pharmaceutical drugs to treat a condition.

Two conventional treatments for hepatitis C have been authorised by the government for use in Australia: pegylated interferon as monotherapy, or pegylated interferon and ribavirin as combination therapy. Combination therapy is used as standard unless the patient cannot take ribavirin. Combination therapy has a higher success rate in clearing the hepatitis C virus than pegylated interferon by itself.



Conventional treatments aim first to eliminate the virus, but also to prevent chronic hepatitis C infection progressing to cirrhosis or liver failure or to reduce the symptoms related to chronic (or long term) infection.

If you are considering monotherapy or combination therapy, your doctor can provide an initial assessment and refer you to your nearest treatment centre, usually located within a hepatitis clinic at a major hospital. Here a specialist will assess your options for treatment. This assessment will be based on certain criteria and the results of various tests.

Before treatment, you need to be fully informed about potential side effects, and how they may affect your relationships, work and lifestyle. Questions to ask your doctor before starting treatment are listed at the back of this booklet.

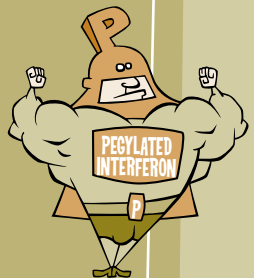


Pegylated Interferon

Interferons are natural proteins produced by the human body to help defend itself against viral infection. They interfere with the ability of the hepatitis C virus to copy itself and spread throughout the body.

The pegylated interferon used in the treatment of hepatitis C is a synthetic compound almost identical to the natural one. Studies have shown that large doses of this synthetic compound can boost the body's immune system, and slow down or stop the progression of liver disease caused by hepatitis C.

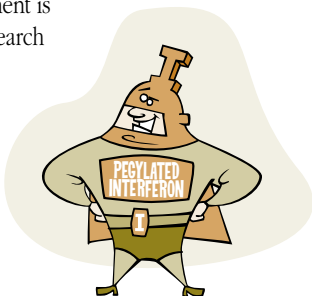
Pegylated interferon is different to standard interferon (non-pegylated). It has been changed so that it stays in the body for longer and needs only to be injected once per week instead of 3 times per week. It is more effective at clearing the hepatitis C virus than standard interferon.



More about ribavirin & pegylated interferon

Pegylated interferon treatment is self-administered by a subcutaneous (under the skin) injection once a week for either 24 or 48 weeks. This means that you inject the drug under your skin, usually in the stomach or upper leg region. Instruction on how to inject pegylated interferon is provided before you start treatment.

The course of treatment must be continuous so that the effects of the pegylated interferon build up over time. Your doctor and specialists at the treatment centre will monitor your response to the treatment. They will take regular blood tests to check levels of the enzymes in your blood (referred to as alanine aminotransferase levels or ALT). If your ALT levels show you are not responding to the pegylated interferon within the first three months, the treatment is stopped. This is because research shows that you are unlikely to respond to further treatment after this time.



Side effects of pegylated interferon

Side effects from pegylated interferon will vary for each person. Some people report no side effects. Others may have flu-like symptoms, especially in the first few months of treatment, or become forgetful, short-tempered, tired or depressed. Fortunately, most side effects disappear once treatment has stopped.

Life threatening complications from treatment with pegylated interferon are rare.

It is difficult to predict how you might respond to treatments, and what side effects you might experience. Before starting treatment, ask your doctor and treatment specialist about all the possible side effects you may experience.

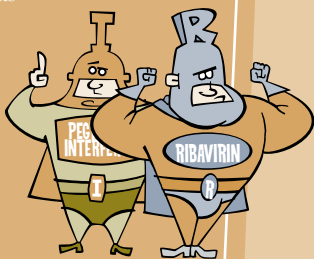
Pegylated interferon and ribavirin are packaged together for combination treatment. The length of treatment varies depending on your tolerance to the drugs, response to the treatment and your genotype (the strain of virus).

Ribavirin

Ribavirin is an antiviral drug, which has been used successfully to treat other viruses, but is ineffective as a sole treatment for hepatitis C.

It is not known exactly how ribavirin works in the treatment of hepatitis C. While it brings down the level of liver enzymes, it has little or no effect on hepatitis C viral load, and liver enzyme levels will often go back up within weeks of stopping ribavirin. The combination of ribavirin with pegylated interferon results in a better treatment response than with either drug used on its own.

Ribavirin is manufactured as a capsule or tablet and is taken orally, usually twice a day.



How long does treatment last?

People with genotypes 2 and/or 3 are usually treated for 24 weeks. Those with other genotypes are usually placed on therapy for 48 weeks. This may also depend of the level of damage that your liver has sustained.

If you are on treatment for 48 weeks, you will be blood-tested at 12 and 24 weeks to see if you have had a treatment response (i.e. if the amount of virus in your blood has fallen dramatically). If not, you will most likely have your treatment stopped, as you are unlikely to clear the virus.

People who are on therapy for 24 weeks may not be tested at 12 weeks because of the high likelihood of an Early Viral Response, or EVR in people with genotypes 2 and 3.

Side effects of combination therapy

Side effects of combination therapy vary for each person and may improve as treatment continues.

The side effects are similar to those experienced with pegylated interferon alone: initial fever, chills, muscle aches and headaches. Some people experience tiredness, loss of appetite, insomnia, nausea, vomiting, skin dryness and itching, dry throat, temporary hair thinning, and weight loss.

Ribavirin can also temporarily lower your red blood cell count and platelet count. This may cause tiredness, shortness of breath and less energy. Doctors will closely monitor your blood counts and iron levels during the first few weeks of combination therapy to avoid any serious side effects, such as anaemia (lack of iron in the blood).

Mood swings or depression may also occur. Other side effects such as thyroid disorders may occur but are less common.

Most of these side effects can be managed throughout the treatment process and will stop when treatment ceases.

Ribavirin has been shown to cause birth defects in animals, so combination therapy is not available to women who are pregnant and/or breastfeeding. Men and women must also use adequate contraception during, and for six months after treatment.

Talk to your specialist or treatment centre about the possible side effects of combination therapy and how to manage them.

Effectiveness of combination therapy

Recent clinical trials have shown that people with hepatitis C are more likely to have a sustained (or long term) response with combination therapy than they would with pegylated interferon alone.

The aim of combination therapy is to achieve a sustained viral response, or SVR. This means that the amount of measurable virus in your blood would be greatly reduced or not detectable, and your liver function tests would be normal for at least 6 months after completing treatment. Current research suggests that if a person has a sustained response for six months after combination therapy, there is a good chance that their response will last indefinitely.

How you might respond to combination therapy may be related to several factors:

- your genotype (strain of virus). People with genotype 2 and 3 have been shown to have a response rate of about 80%, whereas people with genotypes 1 and 4 have a response rate of approximately 50%.
- the amount of hepatitis C virus in your blood (viral load).



Age, sex, stage of liver disease and lifestyle might also affect response rates.

Discuss your chances of responding to combination treatment with your specialist or liver clinic nurse.

Eligibility for conventional treatments

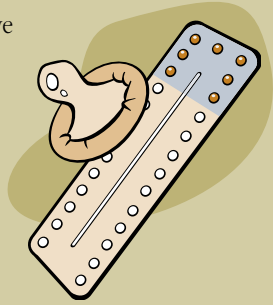
Combination, and monotherapy are provided free of charge by the government under the Pharmaceutical Benefits Scheme (PBS) and is based on an assessment against certain criteria listed under Section 100 of the PBS.

A pharmacy dispensing fee may be payable (around \$20/month).

For people who have not previously received treatment* with either standard or pegylated interferon, the criteria for receiving prescribed pegylated interferon and ribavirin for hepatitis C includes**:

- you must be 18 years of age or over
- you must have tested antibody positive to hepatitis C
- you must have raised ALT levels
- you must have active hepatitis C (tested with PCR)

- you must have had a liver biopsy that shows you have fibrosis. (If you have a bleeding disorder, such as haemophilia, there are other assessments that may be used)
- (for women) you must not be pregnant or breastfeeding, or (for men) your partner must not be pregnant to you
- you must be using contraception, with both partners taking precautions to prevent pregnancy.



** If you have previously received interferon therapy for hepatitis C, you cannot access subsidised pegylated interferon. If this is the case for you, see your treating doctor/specialist. They may be able to help you to find other means of accessing treatment.*

*** These criteria are correct at the time of publication. Treatment regimens are subject to rapid change, and the criteria for PBS subsidised treatment may also change. See your local Hepatitis Council or treating doctor about the inclusion criteria for subsidised treatment.*

People who are on a methadone maintenance program and/or inject drugs, and people co-infected with HIV are eligible for government-subsidised combination therapy.

Other access to monotherapy and combination therapy

Pegylated interferon monotherapy and combination therapy (with ribavirin) can be purchased on prescription through a doctor or specialist. This is an expensive way to access treatment and is not a practical option for most people with hepatitis C.

Un-subsidised costs for combination therapy generally run to approximately \$25,000 per year. On the PBS, patients can expect to pay about \$20 per month dispensing fee for combination therapy.

If you choose to access therapies outside of the PBS, it is important that your treatment regimen is administered according to the product's general marketing guidelines and that your response to treatment is regularly monitored by a specialist.

People who didn't respond to initial monotherapy (non-responders) and those who fall outside the PBS \$100 subsidised treatment guidelines for access to combination therapy, can seek mono or combination pegylated therapy through pharmaceutical industry-sponsored expanded access programs (see glossary p 18).

After Treatment

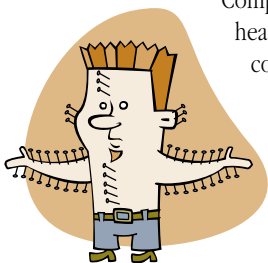
It is important to understand that you may not feel 100% when you first finish treatment and you may not feel well again for a number of months.

Your local Hepatitis Council can provide you with information about what you may experience after finishing or stopping treatment (see Contacts p 24)

Complementary and alternative therapies

Complementary and alternative therapies (or natural therapies) may help manage the symptoms of hepatitis C infection and/or help with side effects of conventional treatment. They describe systems of medicine that are not presently part of current conventional medical practice.

Complementary therapy refers to a health practice when it is used *with* a conventional or mainstream health care approach.

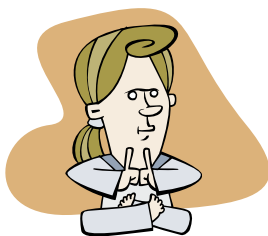


Alternative therapy refers to a health practice when it is chosen instead of a conventional or mainstream health care approach.

Sometimes these terms are used interchangeably.

Complementary and alternative therapies include Traditional Chinese Medicine (TCM), homoeopathy, massage, acupuncture, yoga, meditation, herbal therapies, vitamin and dietary supplements, and aromatherapy. These are just a few of the natural therapies available.

Alternative therapies and/or dietary supplement regimens are provided by qualified practitioners such as nutritionists, dieticians, naturopaths, acupuncturists and herbalists.



Many good resources are available that provide more detailed information about complementary and alternative therapies (contact your local Hepatitis Council for more information). It is important to inform all of your treating practitioners of all treatments

you are using/receiving. These may be conventional (medical) treatments or alternative/complementary therapies.

Information and support

For more information on current treatments for hepatitis C, treatment centres and referrals, talk to your doctor, health clinic or local Hepatitis Council.

Support groups can play an important role in helping you make a decision about whether or not to begin treatment. They can also provide valuable support to you during treatment, especially when you are having trouble in dealing with the side effects of treatment, or even if your treatment is unsuccessful. Many Hepatitis Councils and major metropolitan hospitals have support groups for people undergoing pegylated interferon or combination therapy for hepatitis C.

Contact details of State and Territory Hepatitis Councils are on page 24.

Questions to ask the doctor or specialist before starting conventional treatment

Some people often find going to doctors stressful and confusing.

The questions below can be useful in gaining information from your doctor or specialist about the treatments for hepatitis C. The answers to these questions may help you decide whether or not to use treatment.

If you use these questions, make sure you understand the answers. Ask the doctor to explain any information that you do not understand.

Before deciding to use treatment, you need to be clear about:

- what the treatment is
- how the treatment works, and
- what side effects you can expect.

For a doctor to answer all of the questions below, you can ask for a longer consultation when making your appointment. To prepare yourself for your appointment, try to answer some of the questions by reading this booklet, about the different hepatitis C treatment options.

- What treatment is used for hepatitis C?
- How does the treatment work?
- What tests will I need before hand?
- Is this the best available treatment for me at this point in time?

Discuss any relevant issues like contraception, any travel plans, the potential impact on work or your career.

- How long will I have to take the treatment?

Will it be for 24 or 48 weeks?

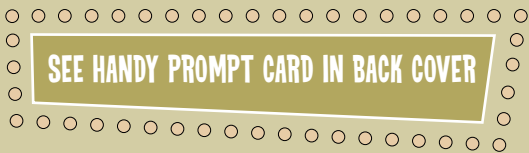
- What are my options if treatment does not work?
- How often will I have to take the treatment, and how is it taken?
- Are there any special instructions for taking the treatment?



Issues to discuss include storing treatment supplies, injections, injecting technique and disposal of injecting equipment.

- Are there interactions with other drugs, foods, alcohol or sunlight?
- What are the side effects of the treatment and how often do they occur?
- Does this treatment have any dangerous side effects? How will I and the doctor deal with side effects?
- If someone accidentally takes my treatment, or I accidentally take too much, what should I do?
- How expensive is the treatment?
- Where do I get the treatment?
- What if I, or my partner, become pregnant while taking this treatment?
- Does the treatment interfere with sexual functions and relationships any way (eg, sterility, impotence, loss of sex drive)?
- If I stop the treatment suddenly, what will happen?
- If I miss a dose, what should I do?
- Are other options available for me?
- What if I have no treatment at all?





GLOSSARY

- ALT** -----> Alanine aminotransferase
- a protein which, when found in blood in elevated quantities, generally indicates liver damage.
- Anaemia** -----> A condition characterised by a lack of haemoglobin in the blood.
- Antiviral** -----> Any agent that interrupts the life cycle of the virus or which stops the virus from entering a cell.
- Cirrhosis** -----> A condition where scar tissue develops in the liver, to the extent where scarring becomes extensive and permanent, and interferes with the normal functioning of the liver.
- Clinical trials** ----> A research activity designed to test a drug or treatment, so as to establish its effectiveness and safety and identify patients who could benefit from such a drug or treatment.
- Endogenous depression** ----> A mental state, characterised by excessive sadness, which arises from causes inside the body.
- Exogenous depression** ----> A mental state, characterised by excessive sadness, which arises from causes outside the body.

- Enzyme** -----> Protein formed in living cells (or produced synthetically) and assisting chemical processes.
- EVR** -----> Early Viral Response. A dramatic fall in viral load (by PCR test) at week 12 of combination or mono treatment.
- expanded access programs** -----> A scheme where, if they don't meet the PBS treatment criteria, a person is assessed and given special access to ribavirin (provided by the pharmaceutical company) and pegylated interferon (provided under the Pharmaceutical Benefits Scheme). Monthly pharmacy dispensing fees (about \$20) will apply in these cases. Sometimes referred to as a Special Access Scheme.
- Fibrosis** -----> Scar formation resulting from the repair of tissue damage. If it occurs extensively in the liver, it is called cirrhosis.
- Genotype** -----> Different genotypes (or strains) of the one virus that are similar enough to be regarded as the same type of virus but have some minor differences in their composition.
- Hepatocellular carcinoma** ----> Cancer of the liver. A malignant tumour arising in the liver, in most cases occurring as a complication of cirrhosis.

- Hepatitis C** -----> Acute or chronic inflammation of the liver caused by the hepatitis C virus. The term chronic hepatitis C refers to hepatitis C infection of more than six months duration.
- Insomnia** -----> Inability to sleep.
- Interferon** -----> Interferons are proteins produced by the human body to help defend itself against viral infection.
- Molecule** -----> A very small unit of a substance.
- Non-responders** --> People, who after 12 weeks of treatment, fail to have normalised levels of alanine aminotransferase (ALT) in their blood.
- PCR** -----> Polymerase Chain Reaction is technology used for identifying viruses and genotypes, and measuring viral load in blood.
- Pegylated interferon** -----> Interferon that has been modified so that it has a longer action in the body.
- Platelet** -----> The smallest of the cells in the blood which are essential for coagulation (clotting) of the blood.
- Relapsers** -----> People who have been on treatment and whose viral measurement and liver function tests have become abnormal again once treatment is stopped.
- Ribavirin** -----> The drug ribavirin is a nucleoside analogue, which means it can be incorporated into the genetic material of a virus, stopping the virus from replicating or copying itself.

- S100** -----> Section 100 is a particular Pharmaceutical Benefits Scheme listing of certain restricted drugs. The Scheme also establishes the criteria under which patients qualify for treatment.
- Sustained Response** -----> This usually refers to a loss of measurable virus in the blood and normalisation of liver enzymes (liver function tests) that lasts at least six months after treatment ends.
- Viral load** -----> The amount of virus present in a person's bloodstream. It is usually measured by PCR technology and the result is given in number of virus particles per millilitre of blood.

FURTHER INFORMATION

Websites

Hepatitis C Councils

Hepatitis C Council of Victoria –
www.hepcvic.org.au

Hepatitis Council of Western Australia –
www.hepatitiswa.com.au

Hepatitis C Council of New South Wales –
www.hepatitisc.org.au

Hepatitis C Council of Queensland –
www.hepatitisc.asn.au

Hepatitis C Council of South Australia –
www.hepccouncilsa.asn.au

ACT Hepatitis C Council –
www.acthepc.org

NT AIDS and Hepatitis Council –
www.ntahc.org.au

Tasmanian Council on AIDS Hepatitis C and Related
Diseases – *www.tascahrd.org.au*

Australian Hepatitis Council –
www.hepatitisaustralia.com

Other National Organisations

Haemophilia Foundation of Australia –
www.baemophilia.org.au

Australian Injecting and Illicit Drug Users' League
(AIVL) – *www.aivl.org.au*

HealthInsite –
www.healthinsite.gov.au

Books and resources



The following Australian Hepatitis Council resources are available from your state/territory Hepatitis Council. Local councils also produce their own hepatitis C resources.

Australian Hepatitis Chronicle, Issues 1-, 1999-

Contact 01: Post-test Information for Hepatitis C, 2001.

Complementary and Alternative Therapies for Hepatitis C, 2003.

Preparing for Testing, 2001.

Moving on After Treatment, 2002.

Women and Hepatitis C, 2004.

CONTACTS

State & Territory Hepatitis Councils

ACT Hepatitis C Council

Ph: 02 6253 9999

Fax: 02 6253 9992

Info: 1800 803 990

Email: info@acthepc.org

Web: www.acthepc.org

Hepatitis C Council of NSW

Ph: 02 9332 1853

Fax: 02 9332 1730

Hep C Helpline: 02 9332 1599

Info: 1800 803 990 - NSW country

Email: hccnsw@hepatitisc.org.au

Web: www.hepatitisc.org.au

Hepatitis C Council of Victoria

Ph: 03 9380 4644

Fax: 03 9380 4688

Info: 1800 703 003 - VIC country

Email: hepcvic@vicnet.net.au

Web: www.hepcvic.org.au

Hepatitis Council of WA

Ph: 08 9328 8538

Fax: 08 9227 6545

Info: 1800 800 070 - WA country

Email: info@hepatitiswa.com.au

Web: www.hepatitiswa.com.au

Hepatitis C Council of Queensland

Ph: 07 3236 0612

Fax: 07 3236 0614

Info: 1800 648 491 - QLD country

Email: admin@hepatitisc.asn.au

Web: www.hepatitisc.asn.au

Hepatitis C Council of SA

Ph: 08 8362 8443

Fax: 08 8362 8559

Info: 1800 021 133 - SA country

Email: admin@hepcouncilsa.asn.au

Web: www.hepcouncilsa.asn.au

Tasmanian Council on AIDS, Hepatitis and Related Diseases

Ph: 03 6234 1242

Fax: 03 6234 1630

Info: 1800 005 900 - TAS country

Email: mail@tascard.org.au

Web: www.tascahrd.org.au

NT AIDS and Hepatitis Council

Ph: 08 8941 1711

Fax: 08 8941 2590

Info: 1800 890 899 - NT country callers

www.ntahc.org.au

For details of your local peer-based drug user group, contact:

Australian Injecting and Illicit Drug Users League
(AIVL)

Ph: 02 6279 1600

Fax: 02 6279 1610

Email: aivl@aivl.org.au

Web: www.aivl.org.au

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Australian Hepatitis Council

QUESTIONS TO ASK YOUR DOCTOR

- What treatment is used for hepatitis C?
- How does the treatment work?
- What tests will I need beforehand?
- Is this treatment the best available for me at this point in time?
- How long will I have to take the treatment?
- What are some options for the likelihood of treatment failure?
- How will I know if the treatment hasn't worked?
- How often will I have to take the treatment, and how is it taken?
- Are there any special instructions for taking the treatment?
- What are the interactions with other drugs, foods, alcohol or sunlight?
- What are the side effects of the treatment and how often do they occur?

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- Does this treatment have any dangerous side effects? If yes, what are they, how common are they, am I at higher risk of side effects and how will I know I am experiencing a dangerous side effect? How will the doctor deal with side effects?
- If someone accidentally takes my treatment, or I accidentally take too much, what should I do?
- How expensive is the treatment?
- Where do I get the treatment?
- What if I, or my partner, become pregnant while taking this treatment?
- Does the treatment interfere with sexual functions and relationships? (eg sterility, impotence, loss of sex drive).
- If I stop the treatment suddenly, what will happen?
- If I miss a dose, what should I do?
- What other options are available for me?
- What if I have no treatment at all?

