THINKING ABOUT TREATMENT FOR HEPATITIS C?

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

- what treatments are available
- the side effects of treatments
- 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' section and contacts listed at the back of this booklet.

This booklet does not promote one treatment over another. It is designed to provide information to help people with hepatitis C make an informed decision about whether they should consider treatment.

The information and advice provided in this booklet is not intended to replace professional medical advice. People should consult their doctor or specialist before acting on any advice to be sure it is right for their particular health situation.

DECIDING ABOUT TREATMENT

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 can last six to 12 months, so it is important to be well informed about hepatitis C and the available treatments before you begin.

Deciding whether 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 conventional 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 doesn't 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 considering treatment, it's a good idea to find out more about your options. You can get free information and support from:

- Hepatitis C 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.

WHAT TREATMENTS ARE AVAILABLE?

CURRENT treatments for hepatitis C include conventional treatment, such as interferon monotherapy and combination therapy (see pages 4-13). Other treatments include complementary and alternative therapies, such as Traditional Chinese Medicine (page 14).

Combination therapy is the preferred form of treatment, 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 refers to 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: interferon as monotherapy, or interferon and ribavirin as combination therapy.

Conventional treatments aim to eliminate the virus, to prevent chronic hepatitis C infection progressing to cirrhosis or liver failure or reduce the symptoms related to chronic 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.

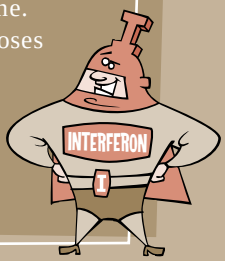
MONOTHERAPY

MONOTHERAPY means using one drug to treat a disease. For people with hepatitis C, it refers to the use of interferon on its own to treat hepatitis C.

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 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.



Interferon treatment is self-administered by a subcutaneous injection three times a week for 12 months. This means that you inject the drug under your skin, usually in the stomach region or upper leg. Initial instruction on how to inject interferon is provided by nurses before you start treatment.

The course of treatment must be continuous so that the effects of the 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 interferon within the first three months, the treatment is stopped. This is because research shows that you are unlikely to respond to further treatment with interferon after this time.

Side effects of interferon monotherapy

Side effects from 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 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.

Effectiveness of monotherapy

Interferon monotherapy is successful in treating some people with hepatitis C. About half of all people treated with interferon respond during treatment but only 20 per cent or less have a sustained response and test PCR negative for the virus six months following treatment. Response rates increase after 12 months of treatment.

Combination treatment, or trials of other forms of interferon (eg pegylated interferon) are available to people who don't respond to the treatment (non-responders) or people for whom the treatment has been unsuccessful (referred to as 'relapsers').

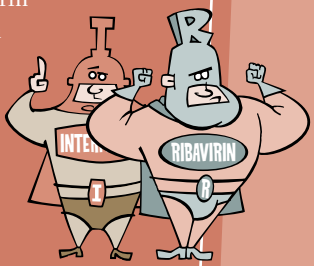
COMBINATION THERAPY

COMBINATION therapy means using more than one drug to treat a disease. For people with hepatitis C, this means using interferon and ribavirin together to treat hepatitis C.

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 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.

Interferon and ribavirin are packaged together for combination treatment. Using combination therapy involves self-administered interferon injections (three times a week) and ribavirin capsules (twice a day) for either six or 12 months. The length of treatment varies depending on your tolerance, response to the treatment and your genotype (the strain of virus).

Your response to combination treatment depends on a number of factors, such as your sex, genotype, and the amount of virus in your blood (see section on 'Effectiveness of combination therapy' below).

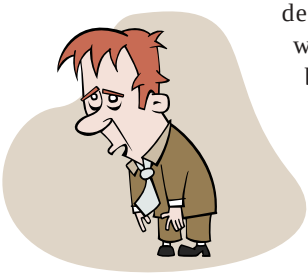
You will be asked to visit your doctor or specialist regularly during and after treatment so that they can monitor your progress through blood tests. Treatment with government-subsidised S100 combination therapy will stop after three months if your viral detection blood test remains positive.

Side effects of combination therapy

Side effects of combination therapy vary for each person and may become less severe as treatment continues.

The side effects are similar to those experienced with 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, 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



decreased energy. Doctors will closely monitor your blood counts and iron levels during the first few weeks of combination treatment 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 interferon alone.

The aim of combination therapy is to achieve a sustained response. This means that the amount of measurable virus in your blood would be less or not detectable,

and your liver function tests would be normal at least six 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 two and three have been shown to have a response rate of between 60 and 70 per cent, whereas people with genotypes one and four have a response rate of between 20 and 30 per cent.
- The amount of hepatitis C virus in your blood.

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

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

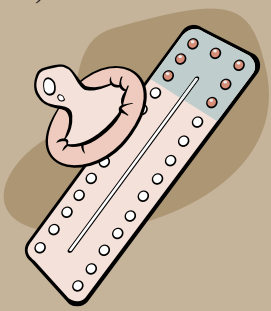
Eligibility for conventional treatments

Interferon monotherapy, and interferon and ribavirin combination therapy are provided free of charge by the government under the Pharmaceutical Benefits Scheme (PBS). For people with hepatitis C, access to government-subsidised therapy is based on an individual's assessment against certain criteria listed under Section 100 of the Pharmaceutical

Benefits Scheme. This criterion is often referred to as PBS S100.

People who have not previously received treatment or who have been unsuccessfully treated with interferon monotherapy, the criteria for receiving prescribed interferon and ribavirin for hepatitis C includes:

- that you have tested antibody positive to hepatitis C
- having raised ALT levels
- having active hepatitis C (tested with PCR)
- 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)
- not being pregnant or breastfeeding, or for men, your partner must not be pregnant to you
- using contraception, with both partners taking precautions to prevent pregnancy.



For people who have relapsed after using interferon monotherapy:

- combination therapy is available although only for 24 weeks. Treatment will stop after 12 weeks if the hepatitis C virus is found in the blood (through a viral detection test or PCR).

For people who have never received treatment:

- combination therapy is available for 48 weeks to people with either genotype one or with severe fibrosis or cirrhosis. If a PCR

test shows detectable levels of the virus after 24 weeks, the treatment will stop.

Combination therapy is limited to 24 weeks for people with other genotypes.

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

Other access to monotherapy and combination therapy

Interferon monotherapy and interferon ribavirin combination therapy 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.

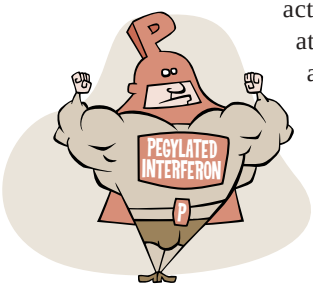
The Pharmaceutical Benefits Scheme S100 criteria do not apply to people who purchase monotherapy or combination therapy privately on prescription. If you choose to access therapies this way, it is important that your treatment regime is administered according to the product's general marketing guidelines 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 S100 subsidised treatment guidelines for access to combination therapy, can seek mono, combination or pegylated treatment through pharmaceutical industry-sponsored Special Access Schemes (see glossary).

PEGYLATED INTERFERON

PEGYLATED interferon is a modified form of the standard synthetic interferon used in the treatment of hepatitis C.

The addition of a molecule (polyethylene glycol) to the standard interferon results in a significant change to the action of the drug. By attaching this molecule, it allows the interferon's antiviral activity to last over a longer time. This means the interferon only needs to be injected once a week instead of three times a week.



The slower clearance rate of pegylated interferon from the body provides a more constant level of interferon circulating in the blood.

The effectiveness of pegylated interferon for people with hepatitis C is still being studied.

Side effects of pegylated interferon

The side effects of pegylated interferon are similar to those experienced from standard interferon, and can vary for each person.

The most common side effects are flu-like symptoms, such as headache, muscle aches, fatigue and fever.

Availability

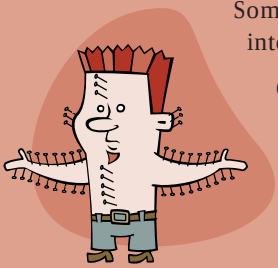
Pegylated interferon is currently only available in Australia from clinical trials and through the compassionate access scheme. Talk to your doctor or specialist about whether pegylated interferon is a treatment option you should consider.

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.

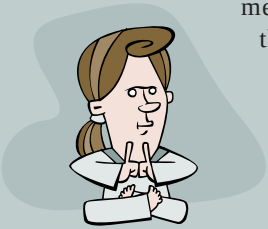
Complementary therapy refers to a health practice when it is used with a conventional or mainstream health care approach.

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, homoeopathy, massage, acupuncture, yoga,



meditation, herbal therapies, vitamin and dietary supplements, and aromatherapy.

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

There are many good resources available that provide more detailed information about complementary and alternative therapies. It is important to consult your doctor and a qualified practitioner of complementary or alternative therapies to obtain more information before starting any therapy.

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 C 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 experiencing difficulties in dealing with the side effects of treatment, or even if your treatment is unsuccessful. Many Hepatitis C Councils and major metropolitan hospitals have support groups for people undergoing interferon or combination therapy for hepatitis C.

Contact details of State and Territory Hepatitis C Councils are on page 25.

Questions to ask the doctor or specialist before starting conventional treatment

Some people find going to doctors stressful and often 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 decide to ask these questions, make sure you understand the answers. Have the doctor explain any information that is not clear in a way that you can understand. Remember that you need to be clear about: what the treatment is; how the treatment works; and what side effects you can expect, before deciding to use treatment.

For a doctor to answer all of the questions below, you may need to 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, so that you are informed about the different hepatitis C treatment options.

- What treatment is used for hepatitis C?

  The doctor should mention interferon and ribavirin.

- How does the treatment work?

- What tests will I need beforehand?

- Is this treatment the best available for me at this point in time?

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

- How long will I have to take the treatment?

  Will it be for six or 12 months?

- 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?

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

- 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?

- 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?

SEE HANDY PROMPT CARD IN BACK COVER

GLOSSARY

ALT → Alanine aminotransferase - a protein which, when found in blood in elevated quantities, generally indicates liver damage.

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.

Compassionate Access Scheme → A scheme where a person is assessed and given special access to ribavirin (provided by the pharmaceutical company) and interferon (provided under the Pharmaceutical Benefits Scheme). Monthly pharmacy dispensing fees will apply in these cases. Sometimes referred to as a Special Access Scheme.

Endogenous depression → A mental state, characterised by excessive sadness, which arises from causes inside the body.

Enzyme → Protein formed in living cells (or produced synthetically) and assisting chemical processes.

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 following 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 → The inability to sleep.

Interferon → Interferons are proteins produced by the human body to help defend itself

against viral infection. The drug interferon (of which there are several different types) is a synthetic compound approved for the treatment of certain viral infections, including hepatitis C.

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.

Platelet The smallest of the cells in the blood which are essential for coagulation of the blood.

Relapsers People who have used interferon (monotherapy) treatment and whose viral measurement and liver function tests have become abnormal again once treatment is stopped. From October 1999, combination treatment has been available in Australia for people who are classed as relapsers under the government's S100 Pharmaceutical

Benefits Scheme (PBS). Relapsers who meet specific criteria are eligible for a subsidised six-month course of combination treatment.

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 interferon treatment.

Special Access Scheme → See compassionate access scheme.

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 READING

Websites

Hepatitis C Council of Victoria - *http://hepcvic.org.au*

Hepatitis C Council of Western Australia - *http://hepccwa.highway1.com.au*

Hepatitis C Council of New South Wales - *http://www.hepatitisc.org.au*

Hepatitis C Council of Queensland - *http://www.hepatitisc.asn.au*

Hepatitis C Council of South Australia - *http://www.hepccouncilsa.asn.au*

ACT Hepatitis C Council - *http://www.acthepc.org*

Australian Hepatitis Council – *http://www.hepatitisaustralia.com*

Haemophilia Foundation Australia - *http://www.haemophilia.org.au*

Books and resources

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Dolan, M. *The Hepatitis C Handbook*. Catalyst Press, 1997.

Farrell, G. 'Hepatitis C Research', *Australian Hepatitis Chronicle*, Issue 2, June 1999.

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- *Antiviral drug treatment*, November 2000
- *Combination drug therapy*, November 2000
- *Complementary therapies*, November 2000
- *Consenting to treatment*, November 2000
- *Hepatitis C genotypes*, November 2000
- *Liver function testing*, November 2000
- *PCR and antiviral drug treatment*, November 2000
- *Response – what does it mean?* November 2000
- *Ribavirin explained*, November 2000
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Acknowledgments

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CONTACTS

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Dickson ACT 2602
ph: (02) 6253 9999
freecall: 1800 803 990
web: www.acthepc.org
email: info@acthepc.org

Hepatitis C Council of NSW
PO Box 432
Darlinghurst NSW 1300
helpline: (02) 9332 1599
1800 803 990 - NSW country
web: www.hepatitisc.org.au
email: hccnsw@hepatitisc.org.au

Territory Health Services
PO Box 40596
Casuarina NT 0811
ph: (08) 8922 8007

Hepatitis C Council of Victoria
Suite 5
200 Sydney Road
Brunswick VIC 3056
ph: (03) 9380 4644
1800 703 003 - VIC country
web: www.hepcvic.org.au
email: hepcvic@vicnet.net.au

Hepatitis C Council of WA
PO Box 8060
Perth Business Centre WA 6849
ph: (08) 9328 8538
1800 800 070 - WA country
web: www.hepccwa.highway1.com.au
email: hepccwa@highway1.com.au

Hepatitis C Council of Queensland
PO Box 179
Albert Street
Brisbane QLD 4002
ph: (07) 3229 3767
1800 648 491 - QLD country
web: www.hepatitisc.asn.au
email: hepcq@hepatitisc.asn.au

Hepatitis C Council of SA
PO Box 782
Kent Town SA 5071
ph: (08) 8362 8443
1800 021 133 - SA country
web: www.hepccouncilsa.asn.au
email: hepcsa@senet.com.au

Tasmanian Council on AIDS and Related Diseases
GPO Box 595
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email: mail@tascard.org.au

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