

DAKLINZA® (daclatasvir) now available on the PBS for the treatment of chronic hepatitis C

- *DAKLINZA provides a treatment option for hepatitis C genotypes 1 and 3 representing more than 90% of Australian patients.*¹

March 1, 2016 – DAKLINZA® (daclatasvir), one of the direct acting antiviral treatments for chronic hepatitis C virus (HCV), is now listed on the Pharmaceutical Benefits Scheme (PBS). DAKLINZA provides specialists and general practitioners with an additional option to manage hepatitis C patients who have this progressive disease.

DAKLINZA, in combination with sofosbuvir (a medicine made by another company), is approved to treat hepatitis C patients with genotypes 1 and 3, including patients co-infected with HIV and those with advanced liver disease (including cirrhosis).² Genotypes 1 and 3 are Australia's most prevalent genotypes, representing more than 90% of hepatitis C patients.¹

Hepatitis C is categorised into six distinct genotypes or disease subtypes.¹

"Different genotypes are treated with different combinations of medicines, which is why additional therapies are important to treat and manage this serious disease," said Associate Professor Dr Paul Gow (Gastroenterologist and Hepatologist).

Genotype 3 has emerged as the most challenging genotype to treat and is associated with faster progression to liver cirrhosis and a higher incidence of liver cancer.³ Affecting an estimated 85,000 Australians (or 37% of hepatitis C patients), genotype 3 is the second most common hepatitis C genotype both globally and in Australia.^{1,4}

More than 230,000 Australians are living with chronic hepatitis C,⁵ with nearly one quarter suffering from severe fibrosis or HCV-related cirrhosis.⁶ Around 2,500 Australians die from hepatitis C each year.⁷ People infected with hepatitis C and also infected with HIV have triple the risk of liver failure or liver-related death.⁸

"People with hepatitis C can live symptom-free for years. But if left untreated, hepatitis can lead to chronic liver disease, liver failure and even death," said Dr Gow.

DAKLINZA, in combination with sofosbuvir, works by stopping the hepatitis C virus from multiplying and infecting liver cells.⁹

"The listing of Daklinza on the PBS provides an additional treatment option for a significant group of patients with chronic hepatitis C that have genotype 3 and are co-infected with HIV," said Mr Brent Pfeifferberger, General Manager, Bristol-Myers Squibb Australia and New Zealand.

"I want to thank the Federal Government and, in particular, Health Minister Sussan Ley for making these new medicines available on the PBS in recognition of hepatitis C patients' high unmet medical need."

DAKLINZA must be administered in combination with sofosbuvir for the treatment of chronic hepatitis C for genotypes 1 and 3.^{2,9}

DAKLINZA Safety Profile

The overall safety profile of DAKLINZA is based on data from 1,679 patients with chronic HCV infection who received DAKLINZA 60 mg once daily in a variety of all-oral regimens and interferon-based regimens. Across clinical studies, DAKLINZA-based regimens have been generally well tolerated with low rates of discontinuation across a range of patients. The DAKLINZA with sofosbuvir regimen resulted in low rates of discontinuation (<1%) due to adverse events (AEs). The rate of serious adverse events (SAEs) was low (4%).² The most common side-effects for DAKLINZA when used in combination with sofosbuvir include tiredness, headache, nausea, joint pain and diarrhoea.^{2,9}

The safety of DAKLINZA for the treatment of hepatitis C has been demonstrated in diverse patient populations that include elderly patients, HIV/HCV co-infected patients and patients with severe hepatic impairment and cirrhosis.²

DAKLINZA must not be administered as monotherapy. Since DAKLINZA is used in combination with sofosbuvir, the contraindications, warnings and precautions applicable to sofosbuvir are applicable to the combination regimen. Refer to the Consumer Medical Information for a list of contraindications.²

About DAKLINZA

DAKLINZA is listed on the PBS in combination with sofosbuvir for the treatment of hepatitis C genotypes 1 and 3, with or without cirrhosis.

DAKLINZA is a direct acting antiviral agent (DAA) against the hepatitis C virus and is a NS5A replication complex inhibitor. DAKLINZA is for oral administration and may be taken with or without food. The recommended dose of DAKLINZA is 60 mg once daily. The recommended duration of treatment is 12 or 24 weeks, depending on the patient's experience with previous treatments.²

About Hepatitis C

In Australia, more than 230,000 people are infected with HCV.⁵ Hepatitis C is a virus that infects the liver and is transmitted through direct contact with infected blood and blood products.¹⁰ Up to 90 percent of those infected with hepatitis C will not spontaneously clear the virus and will become chronically infected.¹¹ According to the World Health Organization, 20 percent of people with chronic hepatitis C will develop cirrhosis and, of those, about 5 to 7 percent of patients may ultimately die of the consequences of infection.¹²

PBS Information: Authority required for the treatment of Chronic Hepatitis C Infection. Refer to PBS Schedule for full restricted benefit information.

DAKLINZA Consumer Medicine Information is available [here](#).

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About Bristol-Myers Squibb in HCV

Bristol-Myers Squibb is focused on helping to eradicate hepatitis C around the world, with a primary emphasis on difficult-to-treat patients, including those millions in countries where population-based HCV solutions remain a high unmet need.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit us at BMS.com or follow us on [LinkedIn](#), [Twitter](#), and [YouTube](#).

Note to Editors: Associate Professor Dr Paul Gow (Gastroenterologist and Hepatologist) has been involved with clinical trials sponsored by Bristol-Myers Squibb. He has received no payment from Bristol-Myers Squibb in relation to this media announcement.

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¹ Department of Health. "Hepatitis C genotypes". Available at: <http://www.health.gov.au/internet/publications/publishing.nsf/Content/phd-hepc-manual-toc~phd-hepc-manual-ch1~phd-hepc-manual-ch1-5>. Accessed January 2016.

² DAKLINZA® (daclatasvir) Product Information, 17 November 2015.

³ Ampuero, J. et al 2014. "Review article: HCV genotype 3- the new treatment challenge". *Alimentary Pharmacology and Therapeutics*;39:686-698.

⁴ Messina et al., "Global Distribution and Prevalence of Hepatitis C Virus Genotypes" *Hepatology*, July 2014

⁵ Kirby Institute, 2015. "HIV, viral hepatitis and sexually transmissible infections in Australia, Annual Surveillance Report 2015". The Kirby Institute for infection and immunity in society. UNSW Australia, NSW.

⁶ Thompson, A. 2016. Australia Research Review. "Product Review. Daclatasvir (Daklinza®) for the treatment of chronic hepatitis C virus (HCV) infection." Available at: <http://www.researchreview.com.au/au/Clinical-Area/Internal-Medicine/Infectious-Diseases/Hepatitis/Product-Review-Treatment-of-Hepatitis-C-Virus-Infe.aspx>. Accessed February 2016.

⁷ Gastroenterological Society of Australia. "The economic cost and health burden of liver diseases in Australia". Available at: https://static1.squarespace.com/static/50ff0804e4b007d5a9abe0a5/t/53321aeee4b09f967eb0c7e5/1395792558684/gesa2013_revised%5B1%5D.pdf. Accessed February 2016.

⁸ Centres for Disease Control and Prevention. "HIV and Viral Hepatitis". Available at: http://www.cdc.gov/hiv/pdf/library_factsheets_hiv_and_viral_hepatitis.pdf. Accessed January 2016.

⁹ DAKLINZA® (daclatasvir) Consumer Medicine Information, 25 March 2015.

¹⁰ Centres for Disease Control and Prevention. "Hepatitis C Information for the Public, Overview". Available at: <http://www.cdc.gov/hepatitis/C/cFAQ.htm#overview> Accessed January 2016.

¹¹ World Health Organizations (WHO). "Hepatitis C: About HCV Infection." Available at: www.who.int/csr/disease/hepatitis/whocdscsrlyo2003/en/index3.html Accessed January 2016.

¹² World Health Organization (WHO). "Hepatitis C." Available at: <http://www.who.int/csr/disease/hepatitis/Hepc.pdf>. Accessed January 2016.