

sanofi-aventis

Media Release

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Age restriction for sanofi-aventis' Rilutek now lifted

Sydney, 24 January 2007: Sanofi-aventis has welcomed the Federal Government's decision to lift the age restriction applied to Rilutek® on the Pharmaceutical Benefits Scheme. Rilutek® was previously available on authority for people under 75 years of age with Amyotrophic Lateral Sclerosis (ALS). As of 1 February 2007, it will be available without the age restriction for all people with ALS.

"While riluzole is not a cure, it is the only treatment available for people diagnosed with ALS, a form of Motor Neurone Disease (MND) and can extend survival by six months," said Associate Professor Matthew Kiernan, Consultant Neurologist, Prince of Wales Hospital. "This is particularly significant for people with ALS whose life expectancy after the onset of symptoms is an average of three to five years."

According to sanofi-aventis, prior to this announcement, access to Rilutek® for patients over 75 years was made by the company on a compassionate supply basis. The decision to lift the age restriction is a good outcome for Rilutek® and provides all newly diagnosed patients with equal access to the treatment and its benefits.

"MND is an extremely unfair disease. Most people with the disease gradually lose control of their muscles, resulting in paralysis and increasing levels of disability. In the majority of cases the intellect and memory are not affected, nor are the senses of sight, hearing, taste, smell and sensations," said Rodney Harris, Chief Executive Officer, Motor Neurone Disease Victoria. "Rilutek is the only treatment that offers people with MND some hope. It may increase their life expectancy and can increase their quality of life."

MND currently affects approximately 1,200 Australians(1). It is the name given to a group of diseases, including ALS, in which the nerve cells controlling the muscles that enable us to move, speak, breathe and swallow undergo degeneration and die. The life expectancy for people diagnosed with Motor Neurone Disease is significantly shortened and most will eventually die from respiratory insufficiency or from lung infections(2).

Rilutek® is the only medicine currently available in Australia for the treatment of ALS, it was first registered by the TGA in May, 2002. Rilutek® is only available on authority prescription from a specialist.

ENDS

For further information or interviews, please contact: Kristy Chong, sanofi-aventis (02) 8666 2364 or 0412 104 885

For further information about MND and its impact on people, please contact: Carol Birks, MND Australia (02) 98165322 or 0408 461 932

NOTES TO EDITOR

About Rilutek RILUTEK® (riluzole) 50mg Tablets

Indications: Treatment of patients with amyotrophic lateral sclerosis (ALS).

Contraindications: Hypersensitivity reactions to riluzole or any excipient. Hepatic disease or hepatic impairment. Pregnancy or lactation.

Precautions: Liver impairment (history of abnormal liver function, elevated serum transaminase, bilirubin and/or GGT levels).

Periodic monitoring required (refer to full PI). Riluzole should be discontinued if the ALT levels increase to five times the ULN. Renal insufficiency. Neutropenia. Pregnancy Category B3. Rilutek must not be used in pregnant or lactating women.

Interactions: Riluzole may potentiate the hypnotic effects of hexobarbitone and chlorpromazine. Potential interactions may occur when riluzole is given concurrently with other agents that affect or are metabolised by CYP 1A2.

Adverse Reactions: Unstable angina, atrial fibrillation, cardiac failure. Gastrointestinal disorder, pancreatitis, gastric ulcer, gastrointestinal haemorrhage, gastrointestinal irritation, melaena. Condition aggravated, malaise, weakness, pyrexia.

Hepatitis, jaundice, hepatic function abnormal, hepatocellular damage. Hypersensitivity. Abnormal hepatic, renal & haematological laboratory investigations. Dehydration. Motor dysfunction, paraesthesia nec, completed suicide, confusion, delirium, hallucination, personality change due to a general medical condition. Respiratory failure, asphyxia, respiratory distress. Dermatitis. Anaemia, erythropenia, leucopenia, thrombocytopenia. Please refer to the full PI.

Dosage: The recommended daily dose in adults or elderly is 100 mg (50 mg every 12 hours). Due to the reduction in absorption observed when administered with high fat meals, Rilutek should not be taken with a fat containing meal.

PBS Information: Authority required. Refer to PBS schedule for full authority information.

About Sanofi-aventis

Sanofi-aventis is the world's third largest pharmaceutical company, ranking number one in Europe. Backed by a world-class R&D organisation, Sanofi-aventis is developing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine, vaccines. Sanofi-aventis is listed in Paris (EURONEXT : SAN) and in New York (NYSE : SNY).

References:

(1). Kiernan, MC. Riluzole: a glimmer of hope in the treatment of motor neuron disease. Med J Aust 2005; 182:319-320

(2). <http://www.mnd.asn.au/morefacts.html>