

Health Warning on Smoking Drug

The anti-smoking pill Zyban could trigger a psychotic episode in people with schizophrenia and should be used with caution, doctors have warned. Concerns about the drug, which has generated more than 100,000 prescription requests since it became available on the Pharmaceutical Benefits Scheme on February 1, were raised on Monday by psychiatrists and general practitioners working on guidelines to help people with mental illness quit smoking.

There have been 68 reports of suspected adverse events related to Zyban in Australia since the drug went on sale in November, including 24 reports of psychological disturbances and one death.

The Therapeutic Goods Administration said yesterday a patient died after suffering a massive lung clot (pulmonary embolus) about three days after stopping Zyban, but it had not yet been possible to establish or exclude a causal link with the drug.

The British health department is also monitoring Zyban after receiving notification of 18 deaths possibly associated with the drug. Graham Meadows, senior lecturer at the University of Melbourne's psychiatry department, said people with schizophrenia had at least double the smoking rates of the general population and it was a high priority to help them cut back or stop.

But Dr Meadows said Zyban, the world's first non-nicotine anti-smoking pill, could cause more problems for people vulnerable to psychosis, which includes anybody who has experienced a psychotic episode. He said he did not know of any cases of Zyban triggering psychosis but the concerns were based on the drug's pharmacological properties and the fact that in studies of depressed people, higher doses of Zyban had provoked symptoms with "a psychotic flavor".

"There is a possible and as yet unquantified and possibly significant risk that it might precipitate a psychotic episode," Dr Meadows said. "It's not a blanket prohibition ... but there's certainly reasons for being very cautious and to be watching patients extremely carefully."

A spokeswoman for drug company GlaxoSmithKline, which makes the drug, said many general practitioners had been calling the company to see if it was safe to prescribe Zyban to patients with schizophrenia. The spokeswoman said that while Zyban was not contraindicated for people with mental illness, it had not been evaluated in people with schizophrenia.

"We just have to be a bit careful and we are telling them that it should be used with extreme caution and only initiated by a psychiatrist and not GPs," the spokeswoman said.

She said there had been no deaths during clinical trials for Zyban and no evidence that the drug caused any of the deaths.

There was a chance that one in 1000 people taking Zyban would have a seizure and people taking anti-psychotic medication were already warned against taking Zyban because they had a lowered threshold for seizures.

Sane Australia director Barbara Hocking said her organisation did not want to discourage people with schizophrenia from giving up smoking but there were many alternatives to help reduce or quit smoking besides the new drug. Listing on the PBS slashed the cost of Zyban from \$280 for a two-month supply to \$21.90 and \$3.50 for concession holders.

It is not recommended for use by people who suffer seizures, have a history of eating disorders, or by pregnant or breastfeeding women.