▼Zyban (bupropion hydrochloride) - safety update

Remember Zyban is contraindicated in patients with previous or current seizure disorder.

Zyban was licensed in June 2000 as an aid to smoking cessation in combination with motivational support in nicotine-dependent patients. Information on the safety profile of Zyban can be found in the authorised Summary of Product Characteristics (SPC), and the Patient Information Leaflet (PIL). Up to 31 March 2002 it is estimated that 540,000 patients have received Zyban in the UK.

Up to 24 July 2002, a total of 7,630 reports of *suspected* adverse reactions have been received via the Yellow Card Scheme in the UK. The reactions most commonly reported through the Yellow Card Scheme are shown in the table below - all of these are recognised reactions and listed in the SPC and PIL. It is important to note that the *suspected* reactions are not necessarily caused by the drug and may relate to other factors such as nicotine withdrawal, other illnesses or other medicines taken concurrently.

Reported reaction	Number of reports	Reported reaction	Number of reports
Urticaria	**996**	**Dry mouth**	**245**
Insomnia	**994**	**Palpitations**	**244**
Rashes	**984**	**Vomiting**	**234**
Headache	**779**	**Dyspnoea**	**234**
Dizziness	**747**	**Agitation**	**204**
Nausea	**642**	**Increased Sweating**	**204**
Depression	**473**	**Abdominal Pain**	**189**
Angioedema	**433**	**Seizures**	**184**
Pruritus	**377**	**Chest Tightness**	**181**
Tremor	**352**	**Arthralgia**	**179**
Chest pain	**352**	**Malaise**	**174**
Anxiety	**315**	**Constipation**	**165**

(Please note that many reports contain more than one of the above-mentioned reactions, and therefore the sum of the number of reports in this table exceeds the total number of reports received for Zyban.)

Zyban is associated with a dose-related risk of seizure with an estimated incidence of approximately 0.1% (1/1,000). There have been 184 reports in the UK of seizures *suspected* as being associated with the use of Zyban. In approximately one-half of the reports, patients had either a past history of seizure(s) and/or risk factors for their occurrence.

To reduce the risk of seizures, prescribers are reminded that Zyban is contraindicated in patients with a current seizure disorder or any history of seizures, with current or previous diagnosis of bulimia or anorexia nervosa, with a known central nervous system (CNS) tumour, and those experiencing abrupt withdrawal from alcohol or benzodiazepines.

Furthermore, Zyban should not be prescribed in patients with other risk factors for seizures unless there is compelling clinical justification for which the potential benefit outweighs the increased risk of seizure. Such risk factors include concomitant use of any drug known to lower the seizure threshold (including antipsychotics, antidepressants, antimalarials, theophylline, systemic steroids, tramadol, quinolones and sedating antihistamines), alcohol abuse, a history of head trauma, diabetes treated with hypoglycaemics or insulin and use of stimulants or anorectic products. In such patients a lower dose of 150mg daily throughout the entire treatment period should be considered.

To date there have been 60 reports of *suspected* adverse reactions to Zyban which had a fatal outcome. In the majority of these cases the individual's underlying condition may provide an alternative explanation. Cardiovascular disorders including myocardial infarction and cerebrovascular disorders including stroke were the reported cause of death in 70% of these reports. In 14 of these reports the individual was not taking Zyban at the time of death.

As with all new drugs, the safety of Zyban remains under close review. Doctors and pharmacists are asked to continue to report all suspected adverse reactions to the MCA/CSM.