Zyban (bupropion hydrochloride) Prescribing Information for Great Britain (GB) & Northern Ireland (NI)

Refer to the Summary of Product Characteristics (SmPC) before prescribing.

Zyban (bupropion hydrochloride): each prolonged release tablet contains bupropion hydrochloride 150mg.

Indication:
Zyban tablets are indicated as an aid to smoking cessation in combination with motivational support in nicotine-dependent patients.

Dosage and Administration:
Zyban is intended for oral use only. There should be an interval of at least 8 hours between successive doses.

Adults: Initial dose is 150mg to be taken daily for six days, increasing on day seven to 150mg twice daily.
Paediatric population: Use in patients under 18 years of age is not recommended.
Elderly: Use with caution; recommended dose is 150mg once a day.
Hepatic impairment: Use with caution. In patients with mild to moderate impairment the recommended dose is 150mg once a day.
Renal impairment; Use with caution; the recommended dose is 150mg once a day.

It is recommended that treatment is started while the patient is still smoking and a "target stop date" set within the first two weeks of treatment with Zyban, preferably in the second week. Zyban should be used in accordance with smoking cessation guidelines. Prescribers should assess the patient's motivation to quit. Patients should be treated for 7-9 weeks. If at seven weeks no effect is seen, treatment should be discontinued. Although discontinuation reactions are not expected with Zyban, a tapering-off period may be considered.

Contraindications:
Contraindicated in patients with; hypersensitivity to bupropion or any of the excipients, current seizure disorder or any history of seizures, known central nervous system (CNS) tumour, current or previous diagnosis of bulimia or anorexia nervosa, history of bipolar disorder, severe hepatic cirrhosis. Also contraindicated in patients undergoing abrupt withdrawal from alcohol or any medicinal product known to be associated with risk of seizures on withdrawal (in particular benzodiazepines and benzodiazepine-like agents),
Concomitant use of Zyban and monoamine oxidase inhibitors (MAOIs) is contraindicated. At least 14 days should elapse between discontinuation of irreversible MAOIs and initiation of treatment with Zyban. For reversible MAOIs, a 24-hour period is sufficient.
Zyban should not be administered to patients being treated with any other medicinal product containing bupropion.

Precautions:
Please consult the Summary of Product Characteristics (SmPC) before prescribing.
There is an increased risk of seizures occurring with the use of Zyban in the presence of predisposing risk factors which lower the seizure threshold. Must only be used (maximum dose of 150mg daily) if there is a compelling clinical justification for which the potential medical benefit of smoking cessation outweighs the potential increased risk of seizure.
In patients with a known history of psychiatric illness, psychotic and manic symptomatology have been reported.
Depression, rarely including suicidal ideation and behaviour (including suicide attempt), have been reported in early treatment course in patients undergoing a smoking cessation attempt and also reported with Zyban. Cases of severe hypertension requiring acute treatment have been reported in patients receiving Zyban. Caution is advised in patients with Brugada syndrome or risk factors such as a family history of cardiac arrest or sudden death. Can Interfere with urine testing resulting in false positive readings, particularly for amphetamines. Post-marketing reports of serotonin syndrome, a potentially life-threatening condition, when Zyban is co-administered with a serotonergic agent, such as Selective Serotonin Reuptake Inhibitors (SSRI) or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs).

Interactions with other medicinal products:
Zyban inhibits metabolism by cytochrome P450 2D6. Concomitant therapy with medicinal products with narrow therapeutic indices that are predominantly metabolised by CYP2D6 should be initiated at the lower end of the dose range of the concomitant medicinal product. Such medicinal products include certain antidepressants (e.g., desipramine, imipramine, paroxetine), antipsychotics (e.g., risperidone, thioridazine), beta-blockers (e.g., metoprolol), and Type 1C antiarrhythmics (e.g., propafanone, flecainide). Drugs which require metabolic activation by CYP2D6 in order to be effective (e.g., tamoxifen), may have reduced efficacy, whenever possible avoided during tamoxifen treatment. Nicotine, administered transdermally by patches, did not affect the pharmacokinetics of bupropion and its metabolites. Co administration of digoxin with bupropion may decrease digoxin levels.
Please consult the SmPC for interactions.

Side effects:
Very common (≥1/10): insomnia. Common (≥1/100 and <1/10): Hypersensitivity reactions such as urticaria, depression, agitation, anxiety, tremor, concentration disturbance, headache, dizziness, taste disorders, dry mouth, gastrointestinal disturbance including nausea and vomiting, abdominal pain, constipation, rash, pruritus, sweating, fever.
Consult SmPC for other adverse reactions.

Legal classification: POM.
Marketing authorisation (MA) numbers and basic NHS cost: PL 10949/0340, 60 tablet packet=£41.76
MA Holder: Glaxo Wellcome UK Ltd, trading as GlaxoSmithKline UK, GSK Medicines Research Centre, Gunnells Wood Road, Stevenage, Hertfordshire. SG12 NY, United Kingdom.
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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.