Patient Group Direction for the Supply of Bupropion (Zyban[tm])

The above named Patient Group Direction (PGD) has been written by:			
Position of Signatory	**Name**	**Signature**	**Date**
Doctor	Dr Subha Thiyagesh		09/03/2022
Pharmacist	Kate Dewhirst		
Pharmacist	Mark Payne		02/03/2022

The above named Patient Group Direction (PGD) has been approved and authorised for use by:			
Position of Signatory	Name	Signature	Date
Medical Director	Dr Subha Thiyagesh		25/03/2022

Characteristics of staff to whom the Patient Group Direction applies.

Qualifications required	Pharmacist registered with General Pharmaceutical Council, working within and for a pharmacy with an agreement with Yorkshire Smokefree to provide bupropion under PGD. It is the responsibility of the individual pharmacist to ensure that they and their staff are competent in all aspects of supply of bupropion. This PGD will only apply whilst the pharmacist is employed or contracted/working at the time in an accredited Pharmacy.
Additional requirements	Accredited pharmacies will have a suitable private consultation room / area which are available for all client consultations. The pharmacy must have facilities for measuring blood pressure. Blood pressure must be measured prior to issuing a supply under the PGD. The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

Date of implementation of this PGD - 1st March 2022
Date of review of this PGD/Date expires - 28th Feb 2025

Name	Bupropion Hydrochloride (Zyban[tm])
Legal Status	Prescription Only Medicine
Type	Modified release tablet

Description:	**Bupropion Hydrochloride 150mg MR Tablet**
Dosage:	**Adult** Initially 150 mg daily for 6 days, then 150 mg twice daily (max. per dose 150 mg), minimum 8 hours between doses; period of treatment 7–9 weeks, start treatment 1–2 weeks before target stop date, discontinue if abstinence not achieved at 7 weeks, consider maximum 150 mg daily in patients with risk factors for seizures; maximum 300 mg per day. **Elderly (over 65 years)** 150 mg daily for 7–9 weeks, start treatment 1–2 weeks before target stop date, discontinue if abstinence not achieved at 7 weeks; maximum 150 mg per day. **Patients with hepatic impairment** Bupropion is extensively metabolised in the liver to active metabolites, which are further metabolised. No statistically significant differences in the pharmacokinetics of bupropion were observed in patients with mild to moderate hepatic cirrhosis compared with healthy volunteers, but bupropion plasma levels showed a higher variability between individual patients. Therefore Zyban should be used with caution in patients with mild to moderate hepatic impairment and 150 mg once a day is the recommended dose in these patients. **Patients with renal impairment** Bupropion is mainly excreted into urine as its metabolites. Therefore 150 mg once a day is the recommended dose in patients with renal impairment, as bupropion and its active metabolites may accumulate to a greater extent than usual. The patient should be closely monitored for possible undesirable effects that could indicate high drug or metabolite levels. **Patients with seizure risk factors** Zyban must not be used in patients with predisposing risk factors unless there is a compelling clinical justification for which the potential medical benefit of smoking cessation outweighs the potential increased risk of seizure. In these patients, a maximum dose of 150mg daily should be considered for the duration of

	treatment.
Indication for treatment	Smoking cessation in combination with motivational support in nicotine-dependent patients
Route to Administration:	Oral
Total dose, duration of treatment, total treatment quantity:	Maximum duration of treatment – 9 weeks For patients taking 150mg OD, 60 tablets will be supplied. For patients taking 150mg BD, 2 x 60 tablet supplies will be made.
Storage of Medication:	Do not store above 25°C. Store in the original package.

Criteria for administration	• Over 18 years of age • Patient wanting to stop smoking • Patient receiving motivational support from Yorkshire Smokefree
Groups excluded from treatment (Contraindications):	• Hypersensitivity to bupropion or any of the excipients identified in the PIL • Patients with a current seizure disorder or any history of seizures. • Patients with a known central nervous system (CNS) tumour. • Patients who, at any time during treatment, are 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). • Current or previous diagnosis of bulimia or anorexia nervosa. • Severe hepatic cirrhosis. • Currently taking monoamine oxidase inhibitors (MAOIs). At least 14 days should elapse between discontinuation of irreversible MAOIs (tranylcypromine, isocarboxazid, phenelzine) and initiation of treatment with bupropion. For reversible MAOIs (moclobemide), a 24 hour period is sufficient. • History of bipolar disorder as it may precipitate a manic episode during the depressed phase of their illness. • Patients being treated with any other medicinal product containing bupropion as the incidence of

	seizures is dose dependent and to avoid overdosage. • Patients who have previously experienced a seizure while taking bupropion. • Pregnant or breast feeding • Blood pressure >140/90mmHg on measurement
Precautions	• All ptients should have their blood pressure measured prior to being issued with a supply • All patients should be assessed for predisposing risk factors for seizures, which include: ○ concomitant administration of other medicinal products known to lower the seizure threshold ○ alcohol abuse ○ history of head trauma ○ diabetes treated with hypoglycaemics or insulin ○ use of stimulants or anorectic products. • Renal impairment • Hepatic impairment
Action if patient excluded:	Refer to seek advice from Medical Practitioner or refer back to Yorkshire Smokefree

Action if patient declines treatment:	Consider other treatment options or refer to appropriate Medical Practitioner or refer back to Yorkshire Smokefree
Potential mild adverse reactions	Agitation; anxiety; depression; dizziness; dry mouth; fever; gastro-intestinal disturbances; headache; impaired concentration; insomnia (reduced by avoiding dose at bedtime); pruritus; rash; sweating; taste disturbance; tremor
Severe adverse reaction	Agitation, agression, anorexia; asthenia; chest pain; confusion; flushing; hypertension; tachycardia; tinnit us; visual disturbances abnormal dreams; ataxia; blood-glucose changes; depersonalisation; dystonia; exacerbation of psoriasis; hallucinations; hepatitis; hostility; impaired memory; incoordination; irritability; jaundice; palpitation; p araesthesia; postural hypotension; seizures; Stevens-Johnson syndrome; tachycardia, twitching; urinary frequency; urinary retention; vasodilatation
Procedure for reporting adverse drug reactions:	Inform Yorkshire Smokefree. Yellow card scheme
Written and verbal advice for	All patients should be given the Patient information leaflet

patient/carer	in the box (PIL) Specific advice should be given with regards to symptoms of depression and anxiety associated with withdrawal from nictotine
Record of supply/administration	Complete voucher and record on PMR and Quitmanager The pharmacy must inform the GP that a supply has been issued, an advice note to facilitate this is included.
Follow-up	Patient will be followed up via Yorkshire Smokefree.
References	Current Edition BNF Specific Product Characteristics Zyban update 22nd June 2021

Management of Patient Group Direction

This Patient Group Direction is to be read, agreed to and signed by all registered Pharmacists it applies to.

I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct.

Name of Pharmacist	Signature of Pharmacist	Date Signed

NHS
Yorkshire
Smokefree Service

GP advice note

Notification of supply of Bupropion (Zyban) to your patient through the Bupropion PGD

Patient Name	
Address	
Date of Birth	

Dear Doctor

I have supplied the following stop smoking medication to your patient named above, through the South West Yorkshire NHS Foundation Trust/Yorkshire Smokefree Patient Group Direction for the Supply of Bupropion (Zyban) Tablets of which I am an accredited Pharmacist.

Bupropion 150mg Tablets 1 x 60 150mg bd	
Bupropion 150mg Tablets 1 x 60 150mg od	

Pharmacist Name **Date of supply**

Name and Address of Pharmacy