



This Patient Group Direction (PGD) must only be used by community pharmacists who have been named and authorised by their organisation to practice under it. The PGD must only be used by accredited pharmacists working in conjunction with the Nottinghamshire County Council commissioned Specialist Stop Smoking Service, ABL Health Ltd.

Patient Group Direction

for the supply of

Varenicline tablets

by Community Pharmacists in Nottinghamshire
as part of the Stop Smoking Service

Version: 1:0

Effective from: 01.04.2020




Expires: 31.03.2023

Change History:

Version number	Change details	Date
1.0		

PGD development team	
Donal O'Donoghue	Medical Director, ABL Health Ltd
Karen Baker	Lead Pharmacist, ABL Health Ltd
Elizabeth Woodworth	Head of Smoking Cessation Services, ABL Health Ltd

PGD authorisation

Name	Job title and organisation	Signature	Date
Lead Clinician:	Medical Director ABL Health LTD: Donal O'Donoghue		<u>15.4.20</u>
Lead Pharmacist:	Lead Pharmacist, ABL Health Ltd: Karen Baker		16/4/20
Person signing on behalf of the commissioners	Director of Public Health Jonathan Gribbin		23/04/2020

Community Pharmacist agreement to practice under this Varenicline 0.5mg and 1mg tablets Patient Group Direction (PGD) for Community Pharmacists

Competency

The pharmacist must complete the Declaration of Competence for the Stop Smoking Service available on the Centre for Pharmacy Postgraduate Education (CPPE) website.

I have read and understood the Patient Group Direction and agree to supply this medication in accordance with this PGD

Name	GPhC Number	Signature	Date

Superintendent or authorising deputy has responsibility to ensure only fully competent, qualified and training pharmacist implement this PGD.

Name	
Signature	
GPhC number	
Date	

	Requirements of registered Community Pharmacists working within this PGD
Professional registration	Community Pharmacists currently registered with the General Pharmaceutical Council (GPhC) and are working in a pharmacy within Nottinghamshire
Competency	The pharmacist must complete the self- declaration of competence in accordance with the Centre for Pharmacy Postgraduate Education (CPPE) stop smoking advice: Pharmacist supply of prescription only medicines via a PGD.
Initial training	Pharmacists will be required to undertake training on the effective implementation of this PGD
On-going training	Pharmacists must ensure their clinical knowledge is up to date by attending relevant training updates and an awareness of current literature, for example Specific Product Characteristics.

Clinical condition

Clinical condition or situation to which this PGD applies	Aid to facilitate smoking cessation in clients who are accessing the Specialist Stop Smoking Service delivered by ABL Health LTD. This will be in accordance with the Service Level Agreement (SLA)
Inclusion criteria	<ul style="list-style-type: none"> • Nicotine dependent users aged 18 years or older identified as sufficiently motivated to quit. • Clients must agree to receive weekly behavioural support from ABL Health Specialist Stop Smoking Service. • The client must reside, work or be registered with a GP within the Nottinghamshire County Council district. • Clients must consent to sharing information with their GP.
Exclusion criteria	<ul style="list-style-type: none"> • Under the age of 18 years • No valid consent • Client not motivated to set a quit date • Clients not registered with a GP • Clients who have experienced serious or concerning adverse effects from a previous course of Varenicline • Pregnant or breastfeeding women • Clients unwilling to disclose a medical history • Known renal impairment or undergoing investigations for renal impairment

	<ul style="list-style-type: none"> • History of convulsions / seizures / taking anti – epileptic medication or with other conditions which potentially lower seizure threshold • Hypersensitivity to Varenicline or any of the product excipients • Currently using other forms of licensed smoking cessation medication (Nicotine Replacement Therapy) • Clients referred to or under investigation by a psychiatrist • Unstable psychiatric illness e.g. schizophrenia, psychosis, bipolar disorder or severe depression <p>N.B Short term episodes of depression, for example: a reaction to a bereavement and does not require treatment are not excluded under this PGD</p> <p>Renal impairment: Based on insufficient clinical experience with Varenicline in clients with end stage renal disease, treatment is not recommended in this client population.</p>
<p>Cautions (including any relevant action to be taken)</p>	<p>Neuropsychiatric symptoms</p> <ul style="list-style-type: none"> • With or without pharmacotherapy, smoking cessation has been associated with the exacerbation of underlying psychiatric illness, for example, depression, changes in behaviour / thinking, anxiety, psychosis, mood swings, depression, aggressive behaviour, rarely suicide ideation and suicide attempt which may be a symptom of nicotine withdrawal. • However, the Eagles study (April 2016) provided evidence that the use of Varenicline in clients with or without a history of psychiatric disorder was not associated with a significantly increased risk of serious neuropsychiatric adverse events compared with placebo. • Clients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood of concern, or suicidal thoughts. • Clients taking Varenicline should be advised to contact their GP if they have worsening cardiovascular symptoms <p>Advice to clients receiving medications affected by stopping smoking</p> <ul style="list-style-type: none"> • The metabolism of some drugs will be affected with the cessation of smoking, resulting in a reduction in the cytochrome oxidase (CYP1A 2) enzyme activity. Therefore, increasing drug plasma concentrations.

	<ul style="list-style-type: none"> • A reduction in doses of warfarin, insulin, cinacalcet, ropinirole, theophylline, methadone, caffeine, chlorpromazine and olanzapine may be required. <p>Medical advice: Clients taking medication affected by smoking cessation should inform their GP of their intention of quitting. Clients taking medication affected by smoking cessation must inform their GP if they subsequently relapse</p> <ul style="list-style-type: none"> • Insulin Clients taking insulin should be alert for signs of hypoglycaemia and encouraged to test their blood glucose more frequently. • Warfarin Clients taking warfarin should contact their anticoagulation clinic to inform them about stopping smoking and to arrange an earlier/more frequent INR test.
Action to be taken if clients are excluded	Discuss alternative treatment options and refer - back to the Specialist Stop Smoking Service

Details of medicine

Name, form and strength of medicine	Varenicline 0.5mg and 1mg (as tartrate) (Champix) brand
Legal category	Prescription Only Medication (POM)
Storage	Blister packs Store below 30 degrees C This medicinal product does not require any special storage conditions
Route / method of administration	Oral, swallowed with or without food
Dose and frequency	<p>Clients should be advised to set a quit date 7-14 days after the initiation of Varenicline</p> <p>Initiation pack (Weeks 1 and 2) Days 1 to 3: 0.5mg once daily Days 4 to 7: 0.5mg twice daily Days 8 to 14: 1mg twice daily</p> <p>Maintenance packs (Weeks 3 – 12)</p>

	<p>Day 15 onwards: 1mg twice daily for 10 weeks, until a total course of 12 weeks has been taken.</p> <p>Dose tapering In clients who have a high risk of relapse, dose tapering may be considered at the end of the 12 weeks treatment. Lower the dose to the end of the treatment to 0.5mg (white tablets) twice daily.</p>
Quantity to be supplied	<p>The GP will be notified within 2 days of the first supply (initiation pack) of Varenicline. The medication will be supplied in 6 instalments. The supply will be based on the client continuing to attend the Stop Smoking Service for regular support.</p> <ul style="list-style-type: none"> • The first pack is the initiation pack containing 11 x 0.5mg (white) tablets and 14 x 1mg (blue) tablets • Five maintenance packs each containing 28 x 1mg (blue) should be supplied in 2 weekly instalments. A total of 12 weeks treatment <p><i>Where clients are unable to tolerate the full dose of Varenicline, a reduced dose throughout the course may be recommended. Clients should be supplied with 28 x 0.5mg tablets (white) in 2 weekly instalments. A total of 12 weeks treatment</i></p>
Labelling	<p>This product must be labelled as for a dispensed medicine and bear all relevant cautionary wording as stated in the BNF. Titration packs must bear the instruction to “take as directed on enclosed leaflet” and other packs to “Take one tablet twice a day”</p>
Maximum treatment period	<p>Clients should be treated with Varenicline for a maximum of 12 weeks. The product license permits an additional 12 - week course. The normal course of 12 weeks can be repeated in abstinent clients to reduce the risk of relapse.</p>
Adverse effects	<p>Common adverse effects are, change in appetite, weight gain, abnormal dreams, insomnia, headache, dizziness, dry mouth, sinusitis, cough, nausea, vomiting, reflux, abdominal pain, constipation, diarrhea, fatigue, rash, myalgia. Uncommon but serious side effects include cerebral vascular accident, atrial fibrillation, psychosis, haematemesis</p>

	<p>Clients reporting hypersensitivity reactions including skin reactions should discontinue treatment and contact their GP immediately.</p> <p>This list is not exhaustive for the full list of adverse effects see the current BNF or the Specific Product Characteristics (SPC)</p> <p>All serious adverse drug reactions should be reported using the yellow card system www.mhra.gov.uk/yellowcard</p> <p>It is a duty of all practitioners to report any safety incidents including all adverse drug reactions to ABL Health Ltd and the clients GP.</p>
<p>Record keeping</p>	<p>A Consultation proforma for the supply of Varenicline using this PGD must be completed and signed, irrespective of whether a supply has been made. Appropriate records must include the following and be clear, precise and legible.</p> <ul style="list-style-type: none"> • Informed consent • Clients name, address and date of birth • Name of GP and address • Dose given • Date of supply • Drug manufacturer, batch and expiry date • Advice given if client declines or is excluded from treatment • Advice given to client if supply of Varenicline is issued • The client`s GP must be notified of the supply and details of any adverse reactions and actions taken by letter. This information must be entered in the client`s medical record (PMR) along with the name and GPhC number of the pharmacists who made the supply • A record of supply must be kept on the pharmacy client medication record system • Client safety incidents, for example, medication errors, near misses and suspected adverse events • The retention of clients records in accordance with PGDs for adults will be 8 years

Client information

Written information and advice to be given to the client	<ul style="list-style-type: none">• Patient Information Leaflet must be supplied with the medication pack• Patient should be warned that the medication may make them sleepy and not to drive or operate machinery if affected. <p>The major reasons for Varenicline failure are:</p> <ul style="list-style-type: none">• Unrealistic expectations• Lack of preparation for the potential for the tablets may cause nausea. This can be reduced by taking the tablet after food and with a full glass of water• Insufficient or incorrect use <p>It is important to ensure the client understands the following:</p> <ul style="list-style-type: none">• The medication works by acting on parts of the brain affected by nicotine• It does not remove all temptation to smoke• Approximately one third of clients may experience mild nausea 30 minutes after taking Varenicline. This reaction usually resolves gradually over the first few weeks and most people tolerate it without problems• Smoking cessation, with or without treatment is associated with various symptoms. Clients should be made aware they may experience any side effects. It may not be clear whether these effects are linked to the medication or to nicotine withdrawal
---	--

References

Electronic Medicines Compendium, *Summary of product Characteristics for Champix*, EMC (Pfizer) www.medicines.org.uk accessed 9th February 2020

British National Formulary electronic version www.bnf.org accessed 9th February 2020

National Institute for Health and Care Excellence. Medicines Practice Guideline 2: *Patient Group Directions*: London: NICE, 2013. Updated 2017
<https://www.nice.org.uk/guidance/mpg2/resources/patient-group-directions-177940194M89>

Smoking and smoking cessation: clinically significant interactions with commonly used medicines. Medicines and healthcare products regulatory agency. Oct 2009
<http://www.gov.uk/drug-safety-update/smoking-and-smoking-cessation-clinically-significant-interactions-with-commonly-used-medicines>

Varenicline for Smoking Cessation. NICE technology appraisals guidance TA123, 2007

www.nice.org.uk/guidance/ta123

Which medicines need dose adjustment when a patient stops smoking? Medicines Q&As. UK Medicines information (UKMI) August 2012

<https://www.sps.nhs.uk/wp-content/uploads/2012/10/NW20QA136.420Smoking20and20drug20interactions.doc>