

VARENICLINE

GG&C PGD ref no: 2022/2380

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Clinical Condition

Indication:	Individuals accessing the NHS GG&C smoking cessation service
Inclusion criteria:	<ul style="list-style-type: none"> • 18 years of age or older • Dependent smoker (i.e. they smoke within 30minutes of waking up and /or find quitting unaided difficult) • Identified as sufficiently motivated to quit • The patient agrees to receive appropriate behavioural support • Client provides consent to information sharing
Exclusion criteria:	<ul style="list-style-type: none"> • Smokers not sufficiently motivated to quit • Individuals not willing to engage in weekly monitoring and support • Known pregnancy or breastfeeding women • Allergy or sensitivity to varenicline or any of its excipients • Individuals with severe renal impairment and end-stage renal disease e.g. on dialysis • Previous history of Stevens-Johnson Syndrome or Erythema Multiforme • Individuals with a history of seizures e.g. epilepsy or conditions where the seizure threshold may be lowered. • Individuals known to be using other smoking cessation aids or vaping

Cautions/Need for further advice/Circumstances when further advice should be sought from the prescriber:	<ul style="list-style-type: none"> • Individuals with known renal impairment. Individuals who have mild to moderate renal impairment may be supplied varenicline under this PGD. No dosage adjustment is necessary for patients with mild to moderate renal impairment. . For individuals who experience adverse reactions that are not tolerable, dosing may be reduced to 1mg once daily. See <i>NHS GGC Smoking Cessation Guidelines for Community Pharmacy</i>. • Individuals on insulin may be supplied with varenicline, however patients should be advised to monitor their blood glucose levels more closely and contact their GP or specialist diabetes service if glucose levels change • Individuals with a history of serious psychiatric illness such as schizophrenia, bipolar disorder or major depressive
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	<p>disorder currently receiving treatment and/or pharmacotherapy</p> <ul style="list-style-type: none"> • Individuals taking warfarin, theophylline or clozapine. • Individuals with a history of cardiovascular disease should be instructed to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.
Action if patient declines or is excluded:	<ul style="list-style-type: none"> • Refer patient to their GP • Discuss alternative products if suitable and/or offer a referral to the Specialist Smoking Cessation service for further assessment
Referral arrangements for further advice / cautions:	Refer to GP or specialist Smoking Cessation Service

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Drug Details

Name, form & strength of medicine:	Varenicline 500mcg and 1mg film coated tablets
Route/Method of administration:	Oral
Dosage (include maximum dose if appropriate):	Days 1 - 3: 500mcg once daily Days 4 – 7: 500mcg tablets twice daily Day 8 to the end of the treatment: 1mg twice daily for 11 weeks. (Reduce to 500mcg twice daily if not tolerated) Maximum single dose 1mg Maximum daily dose 2mg
Frequency:	As above
Maximum or minimum treatment period:	Every attempt should be made to reduce the use of varenicline to zero by the end of 12 weeks. However, Individuals may benefit from taking varenicline for up to an additional 12 weeks to a total of 24 weeks of treatment. The pharmacist should assess the patient to determine whether this would benefit the individual.
Quantity to supply/administer:	Treatment of 500mcg or 1mg tablets to be supplied as per schedule of treatment – See <i>NHS GGC Smoking Cessation Guidelines for Community Pharmacy</i> .
Supply, Administer or Both:	Supply only
▼ Additional Monitoring:*	No
Legal Category:	POM
Is the use outwith the SPC:**	No
Storage requirements:	Store below 25°C.

* The black triangle symbol has now been replaced by European “additional monitoring (▼)”

**** Summary of Product Characteristics**

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<p>Warnings including possible adverse reactions and management of these:</p>	<p>Side effects might include:</p> <ul style="list-style-type: none"> • Nausea (common) • Sleep disorders/ abnormal dreams • Headache • Appetite changes • Dry mouth /taste disturbances • Drowsiness • Dizziness <p>Patients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood or suicidal thoughts.</p> <p>No clinically meaningful drug interactions have been reported. Please refer to current BNF, eBNF http://www.bnf.org/bnf/ or SPC at http://emc.medicines.org.uk/ for full details. Use the Yellow Card System to report adverse drug reactions directly to the CMS. Yellow Cards and guidance on their use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/</p>
<p>Advice to patient/carer including written information provided:</p>	<ul style="list-style-type: none"> • Patient should set a date to stop smoking and start taking varenicline 1-2 weeks before this date. • Tablets should be swallowed whole with plenty of water and can be taken with or without food. • Advice to patients should include specific product advice on dosage, method of administration and side effects • If patient experiences any extreme side effects they should seek medical advice. • Follow-up and obtaining further supplies • Effects on driving or using machinery • At the end of treatment, discontinuation of varenicline has been associated with an increase in irritability, urge to smoke, and/or insomnia in up to 3% of patients. The pharmacist should inform the patient accordingly <p>Patients must be informed that information relating to the supply of varenicline under a PGD needs to be passed to other health service organisations in particular their GP and NHS Scotland to ensure follow-up, proper record keeping and patient safety.</p>
<p>Monitoring (if applicable):</p>	<p>As per the <i>NHS GGC Smoking Cessation Guidelines for Community Pharmacy</i></p>
<p>Follow up:</p>	<p>See <i>NHS GGC Smoking Cessation Guidelines for Community Pharmacy</i></p>

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Staff Characteristics

Professional qualifications:	Those registered as Pharmacists and approved in legislation as able to operate under Patient Group Directions (PGDs) and have current registration.
Specialist competencies or qualifications:	<ul style="list-style-type: none"> • To have satisfactorily completed the approved smoking cessation/varenicline training • To have been accredited as an approved practitioner within the <i>NHS GGC Community Pharmacy Varenicline Prescribing Scheme</i> or equivalent • To have appropriate indemnity insurance arrangements in place • To maintain clinical knowledge appropriate to their practice by attending relevant study days or courses and to make themselves aware of appropriate current literature • To have undertaken appropriate training for working under PGDs for the supply and administration of medicines
Continuing education & training:	All health care professionals working under the Direction will be expected to maintain their competence as specified in hospital, local and national policies. The practitioner should be aware of any change to the recommendations for the medicine listed.

Referral Arrangements and Audit Trail

Referral arrangements	GP or Specialist Smoking Cessation Service
Records/audit trail:	<ul style="list-style-type: none"> • Patient's name, address, date of birth and GP details • Record in PCR and PMR of supply • Reason for inclusion • Advice given to patient • Details of any adverse drug reaction and actions taken including documentation in the patient's medical record via GP • A <i>Varenicline Clinical Risk Assessment Form</i> should be completed for each patient and retained for a minimum of 3 years.

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**References/Resources
and comments:**


- British Nation Formulary (BNF)
- Summary of Product Characteristics (SPC) for Champix®. www.emc.medicines.org.uk. National Institute for Health and Clinical Excellence. Varenicline for smoking cessation. NICE technology appraisal 123, July 2007
- NHSGGC Smoking Cessation Guidelines for Community Pharmacy
[http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/Policies Procedures/GGCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Smoking%20Cessation%20Guidelines%20for%20Community%20Pharmacy.pdf](http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/Policies%20Procedures/GGCClinicalGuidelines/GGC%20Clinical%20Guidelines%20Electronic%20Resource%20Direct/Smoking%20Cessation%20Guidelines%20for%20Community%20Pharmacy.pdf)
- NHS GGC General Policy for Community Supply of Varenicline® by Pharmacists
- Risk of neuropsychiatric adverse events associated with varenicline: systematic review and meta-analysis. BMJ 2015; 350:h1109 <http://dx.doi.org/10.1136/bmj.h1109>

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This Patient Group Direction must be agreed to and signed by all healthcare professionals involved in its use. The original signed copy will be held at Pharmacy Services, Clarkston Court, 56 Busby Road, Glasgow. The PGD must be easily accessible in the clinical setting.

Organisation: **NHS Greater Glasgow & Clyde**


Professionals drawing up PGD/Authors

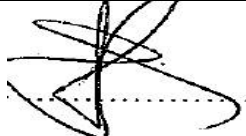
	Designation and Contact Details
<p>*Name: Pamela MacIntyre</p>  <p>Signature 27/04/2022</p>	<p>Designation:</p> <p>E-mail address: pamela.macintyre@ggc.scot.nhs.uk</p>
<p>Name: Hilary Millar</p>  <p>Signature:</p>	<p>Designation: Pharmacy Public Health Improvement Facilitator</p> <p>E-mail address: hilary.millar@nhs.net</p>
<p>Name: Emilia Crighton</p>  <p>Signature:</p>	<p>Designation: Interim Director of Public Health</p> <p>E-mail address: Emilia.crighton@ggc.scot.nhs.uk</p>


*** Lead Author**

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AUTHORISATION:


NHSGG&C PGD & Non-medical Prescribing Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	Signature:	Date:
Dr Craig Harrow		27/04/2022

Lead of the professional group to which this PGD refers:		
Lead Nurse, North Sector in BLOCK CAPITALS	Signature:	Date:
John Carson		27/04/2022

Pharmacist representative of PGD & Non-Medical Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	Signature:	Date:
Elaine Paton		27/04/2022

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Local Authorisation:

Service Area for which PGD is applicable:		Community Pharmacy	
Record/Audit Trail	There must be appropriate records kept and maintained by the pharmacist to enable verification of service provision and training requirements, and provide information for internal and external audit and evaluation purposes.		
Nominated individual who agrees to keep list of practitioners operating under the PGD current and up to date (Lead Professional):			
Name:	Signature:	Designation:	Date:
Alan Harrison		Lead Pharmacist, Community Pharmacy	27/04/2022

PGD DOES NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Authority: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction. I acknowledge that it is a legal document and agree to supply / administer this medicine only in accordance with this PGD.

Name of Pharmacist _____

GPhC Registration Number _____

Email address (preferably NHS) _____

Normal Pharmacy Location

Only one Pharmacy name and contractor code is required for each Health Board (HB) area where appropriate. If you work in more than 2 HB areas please use additional forms.)

If you are a Locum, please supply your home address.

Name & Contractor code HB _____

Locum Home Address _____

Please indicate your position within the pharmacy by ticking one of the following:

Locum Employee Manager Owner

Signature _____ Date _____

Please return to Community Pharmacy Development Team by post: Clarkston Court, 56 Busby Road, Glasgow, G76 7AT. Email: ggc.cpdevteam@nhs.scot

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