



PATIENT GROUP DIRECTION for the Supply of:

Varenicline▼ (Champix®) tablets

By: Accredited Pharmacists

In: Community Pharmacies in Sheffield accredited by Yorkshire Smokefree

- It is the responsibility of the professional working under this PGD to verify that the client fulfils the stated criteria for supply of the treatment concerned
- It is not appropriate to have a PGD in place that is infrequently used by health care professionals because of progressive unfamiliarity with its contents. Any healthcare professional that works to a PGD infrequently should consider whether to cease doing so
- Varenicline is a licensed Prescription Only Medicine as defined by the Medicines Act 1968 and Prescription Only Medicines (Human Use) Order 1997
- Varenicline is required to be intensively monitored and subject to special reporting arrangements for adverse events (Black triangle medicine).
- This PGD takes the place of a Prescription, as defined by The Human Medicines Regulations 2012
- NICE guidance on appropriate use of PGDs requires that a black triangle medicine is included in a PGD only when clearly justified by best clinical practice and that this status is clearly indicated on the PGD
- Clinical indications, Contraindications, and Cautions are as set out in the Summary of Product Characteristics
- Inclusion and Exclusion criteria are summarised within the PGD
- "Off Label" use is not supported by the PGD

It is the responsibility of Clinicians issuing varenicline under the PGD to assess patients suitability against the PGD Inclusion and Exclusion criteria and the SPC Indications/Contraindications. Patients falling outside of these criteria cannot receive varenicline under the PGD.

PGD Review date: 1st March 2019

1. Purpose of the PGD		
For accredited pharmacists to supply varenicline within its licensed indications as an option for smokers who have expressed a desire to quit smoking and who will be supported and monitored by Yorkshire Smokefree or may be referred to an accredited pharmacist by a Yorkshire Smokefree contracted local Stop Smoking Service.		
2. Clinical condition or situation to which this PGD applies		
2.1	Define condition/situation	Varenicline as an option for clients wishing to quit smoking and who are being monitored in the pharmacy
2.2	Criteria for inclusion	<ul style="list-style-type: none"> • Clients over 18 years of age • Tobacco users identified as sufficiently motivated to quit • Tobacco users who are receiving support to stop smoking with Yorkshire Smokefree or a Yorkshire Smokefree contracted Stop Smoking Service • A medical history is taken and documented to establish that there are no contraindications for treatment with varenicline and that any cautions for use are recorded (see Criteria for exclusion). Refer to Appendix 1 for <i>Varenicline voucher Consent</i> has been obtained and recorded. Clients must be informed that information relating to the supply of Varenicline under this PGD needs to be passed to other health service organisations, in particular their GP and their local NHS Smoke Free Service in order to ensure proper record keeping and patient safety. <p>(I know we have 2.4 on consent but not sure the pharmacists will have access to the local consent policy-is this swyt consent policy??)</p>
2.3	Criteria for exclusion	<ul style="list-style-type: none"> • Tobacco users not sufficiently motivated to quit or to use varenicline • Clients under 18 years of age • Sensitivity to varenicline or any of its excipients • Pregnancy/ breastfeeding • Client already receiving varenicline prescribed by GP • Renal impairment or end stage renal disease as decreased clearance by kidney increases side effects. • Epilepsy or history of fits or seizures • Clients who have experienced serious or worrying side effects from a previous course of varenicline • Clients with active or history of psychiatric illness <p><i>The MHRA have warned that there is a possible link between varenicline and psychiatric adverse events, particularly agitation, depression, and suicidal ideation. There is no strong epidemiological evidence from the clinical trials or monitoring data to suggest a causal link and no putative pharmacological mechanism to suggest causality, but this PGD provides a framework that allows for safe supply in the context of this warning.</i></p>
2.4	Client consent (verbal, written,	Informed consent as stated in the local consent policy, including consent to the use of the PGD, and informing GP of supply of

	implied]	varenicline and sharing of information regarding supply with YSF Smokefree
2.5	Action if client excluded	The client should be referred back to the YSF or YSF contracted Stop Smoking Adviser. A new quit date may need to be set and the full range of NRT products may need to be discussed with the client, alternatively the client may wish to make an appointment with their GP to ask for varenicline to be prescribed. Document action in client's medication record (PMR)
2.6	Action if treatment declined by client	The client should be referred back to the YSF or YSF contracted Stop Smoking Adviser. A new quit date may need to be set and the full range of NRT products may need to be discussed with the client, alternatively the client may wish to make an appointment with their GP to ask for varenicline to be prescribed. Document action in client's medication record (PMR) and inform the Service Provider of the outcome
3. Characteristics of staff		
3.1	Class of healthcare professional for whom PGD is applicable & professional qualifications required	Pharmacist registered with General Pharmaceutical Council, working within and for a pharmacy with an agreement with Yorkshire Smokefree to provide varenicline 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 Varenicline. This PGD will only apply whilst the pharmacist is employed or contracted/working at the time in an accredited Pharmacy within Sheffield
3.2	Additional requirements/ specialist qualifications required	Accredited pharmacies will have a suitable private consultation room / area which is available for all client consultations.
3.3	Continued training requirements	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.
4. Description of treatment		
4.1	Generic name of medicine and form (e.g. tablets)	Varenicline (Champix®) 0.5mg and 1mg tablets
4.2	Legal status POM/P/GSL	POM – subject to intensive monitoring requirements (Black Triangle Drug)
	Licensed or unlicensed use [If unlicensed state rationale for use]	Licensed

4.3	Dose [Where a range is applicable include criteria for deciding on a dose]	<p>Days 1 – 3: 0.5 mg (white tablets) once daily</p> <p>Days 4 – 7: 0.5 mg twice daily</p> <p>Day 8 to the end of treatment (up to a maximum of 12 weeks): 1 mg (light blue tablets) twice daily</p> <p>Note: The quit date is often on day 8 of taking Varenicline.</p> <p>Patients who cannot tolerate the adverse effects of varenicline can have the dose lowered temporarily or permanently to 0.5 mg twice daily. (See BNF 4.10.2). The 0.5mg dose must be supplied in the 56 tablet pack.</p> <p>Lower dose to end of treatment (up to 12 weeks in total): 0.5 mg (white tablets) twice daily</p> <p>Clients must attend the same pharmacy for all supplies of Varenicline.</p> <p>A break in treatment of up to 3 days is permitted, after this Varenicline must not be supplied and the client should be referred back to the local Yorkshire Smokefree service.</p>
4.4	Route / method of administration	Oral
4.5	Frequency	Once daily for the first three days, then twice daily thereafter
4.6	Total dose and number of times treatment can be administered; state time frame	<ul style="list-style-type: none"> • Clients should be supplied a 14 day initiation pack and should set a quit date 7 to 14 days after initiation • Clients should be seen by the YSF or YSF contracted stop smoking Advisor weekly for at least 4 weeks after the quit date, then fortnightly. • Clients should be seen by the pharmacist at each supply of Varenicline • Only 14-day or 28-day (for 0.5mg dose only) prescription packs should be used throughout the quit attempt • The treatment course is up to 12 weeks
4.7	Information on follow-up management	Advise to seek medical advice if more severe reactions to medication occur
4.8	Written/verbal advice for client before/after treatment and management	<ul style="list-style-type: none"> • The product should be labelled in accordance with legal requirements • Supply a copy of the manufacturer's patient information leaflet • Swallow tablets whole with a full glass of water immediately after food • Clients should be advised to set a quit date 7 to 14 days after initiation • Product advice to cover dosage, method of administration

		<p>and side effects</p> <ul style="list-style-type: none"> • Client should contact their GP or pharmacist if they experience any serious side effects • The major reasons for varenicline failure are: <ul style="list-style-type: none"> - Unrealistic expectations - Unable to tolerate side-effect of nausea - Insufficient or incorrect use - • It is important to make sure that the client understands the following points: <ol style="list-style-type: none"> 1. Varenicline is an effective medication but effort and determination are also necessary 2. It works by acting on the parts of the brain which are affected by nicotine in cigarettes. 3. It does not remove all temptation to smoke, but it does make abstinence easier. 4. Varenicline is safe, but about a third of clients may experience mild nausea some 30 minutes after taking it. This reaction usually diminishes gradually over the first few weeks, and most clients tolerate it without problems. If client is unable to tolerate due to nausea refer to GP for full review and/or dose reduction 5. Instruct on correct use and daily dose. Use mock product packaging for the explanation. Clients should take varenicline for 7 to 14 days before stopping smoking • At the end of treatment, discontinuation of varenicline has been associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of clients. The pharmacist should inform the client accordingly and discuss or consider the need for dose tapering • No clinically significant drug interactions have been reported
4.9	Communication with client's General Practitioner	<p>In every case when a supply of varenicline is made in accordance with this PGD, the pharmacist must inform the client's General Practitioner (GP) of the supply in a timely manner, by sending the GP copy of the voucher to the client's GP. This must not exceed one calendar month.</p> <p>This applies whether the pharmacy is a Yorkshire Smokefree contracted Stop Smoking Service Provider or not.</p>
4.11	Instructions on identifying, managing & reporting adverse drug reactions	<p>For clients experiencing mild adverse effects after dose increase to 1mg twice daily, and where this is interfering with the quit attempt, consider a temporary or permanent dose lowering to 0.5 mg twice daily. (See BNF 4.10.2) Review at next scheduled appointment.</p> <p>Smoking cessation with or without treatment is associated with various symptoms. For example, dysphoria or depressed mood; insomnia, irritability, frustration or anger; anxiety; difficulty</p>

		<p>concentrating; restlessness; decreased heart rate; increased appetite or weight gain have been reported in clients attempting to stop smoking. No attempt has been made in either the design or the analysis of the CHAMPIX studies to distinguish between adverse events associated with study drug treatment or those possibly associated with nicotine withdrawal.</p> <p>Clients should be asked at every appointment about their mood. If the client develops suicidal thoughts or behaviour they should be told to stop treatment and contact their GP immediately. Where the pharmacy is not the client's Yorkshire Smokefree contracted Stop Smoking Service Provider, the pharmacist should also inform the Service Provider.</p> <p>If the client, family or care givers have concerns about agitation, depressed mood or changes in behaviour varenicline should be stopped immediately.</p> <p>Please refer to current BNF and SPC for full details.</p> <p>Varenicline is required to be intensively monitored and subject to special reporting arrangements for adverse events (Black triangle medicine) – The pharmacist is required to report all adverse reactions to the CSM via yellow card system.</p>
4.12	Arrangements for referral for medical advice	Pharmacist must be able to advise client/parent/carer what action to take in the event of the client experiencing any side effects and the most appropriate action (e.g. dose reduction or medical service to contact).
4.13	Precautions, facilities & supplies	<p>Store in a cool dry place.</p> <p>Order supplies from licensed pharmacy wholesalers.</p>
4.14	Specify method of recording supply sufficient to enable audit trail	<p>Pharmacists are required to keep a record of the consultation and supply in the Patient Medication Records (PMR). The supply of Varenicline should also be recorded on Quitmanager:</p> <ul style="list-style-type: none"> • Client's name, address, date of birth and GP details. • Referring Yorkshire Smokefree contracted Stop Smoking Service Provider. • Date supplied and name of the pharmacist who supplied the medication. • Batch number and expiry date. • Reason for inclusion. • Advice given to client. • Details of any adverse drug reaction and actions taken including documentation in the client's medical record via GP (as well as reporting to the CSM using the 'Yellow Card' reporting system).



5. Audit			
The use of this PGD to be monitored by the service in which it is used.			
6. Management			
6.1 This PGD has been written by:			
Job title	Name	Signature	Date
Lead Pharmacist for Sheffield BDU	Sarah Hudson		31/3/16
Pharmacist Yorkshire Smokefree	Susan Jones		31/3/16
Medical Director	Adrian Berry		1/4/16
6.2 This PGD has been approved on behalf of South West Yorkshire Partnership NHS Foundation Trust and Sheffield by:			
Job title	Name	Signature	Date
Medical Director	Adrian Berry		1/4/16
6.3 Persons permitted to authorise staff they are responsible for to operate this PGD			
Commissioning Manager for the County Council or Deputy			
7. References and Sources of Information			
Service Specification			
Current edition of the British National Formulary			
Manufacturer's Summary of Product Characteristics			
PGD for administration of varenicline tablets by Community Pharmacists within Sheffield			

- It is the responsibility of the Authorising Person to keep this list up to date and in a safe place for reference. Any healthcare professionals who no longer meets the competency requirements or leave the service or practice must be removed from the list; likewise, any new healthcare professionals meeting the competency requirements should be added to the list in order to work under the Patient Group Direction.
- The Authorising Person is only expected to confirm that the Healthcare Professionals meets the minimum training and competency requirements under this PGD. It is the responsibility of the Healthcare Professional themselves and their Professional Body to ensure that they are fit to practice.
- This Patient Group Direction is to be read, agreed to and signed by all healthcare professionals it applies to. The original signed copy should be retained by the Authorised Person with responsibility for PGDs within the pharmacy. A copy should be retained by each pharmacist.



- 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

Healthcare Professionals permitted to supply or administer under this PGD				
Name of Healthcare Professional (Pharmacist)	Signature	Authorised Person with responsibility for PGDs: Commissioning Manager or Deputy	Signature	Date approved



Client Assessment Form – Varenicline (Champix) Voucher

All replies are private & confidential

Serial no: _____ C

For Advisor To Complete – Client Details

Name: _____ Date of Birth: _____

Address: _____

GP Name: _____

GP Practice Address: _____

Advisor details

Advisor Name: _____ Advisor Signature: _____

Contact Telephone Number: _____ Location Client Seen: _____

Date Voucher Issued: _____

For Advisor To Complete	For Pharmacist To Complete		
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Product	Quantity	Supply No.	Date of Supply	Pharmacists Initials
Varenicline Two weeks Titration pack (Supply No. 1 only)	1			
Varenicline 1mg x 28 tablets (Supply No. 2-6 only)	1			
Varenicline 0.5mg x 56 tablets	1			

For Pharmacist To Complete: Please mark with a '✓' in one box next to each statement	Y	N
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1. Aged 18 or above		
2. Tobacco dependant & sufficiently motivated to stop smoking		
3. Agreed to behavioural support during course of Varenicline		
Is the client currently:		
4. Pregnant or breastfeeding?		
Does the client have a history of:		
5. Renal disease?		
6. Epilepsy?		
7. Sensitivity to Varenicline or any of its excipients?		
8. Psychiatric illness?		

All clients must answer YES to Questions 1-3 to be eligible.
If clients answer YES to any of Questions 4 -8, not eligible for Varenicline via the PGD.

For Client To Complete – Consent (in the presence of a pharmacist)

I,(name) confirm that the above information has been discussed with me and is an accurate record of that discussion.

I give consent to the above information being passed to my GP, pharmacist and local smoke free service.

Signature: _____ Date: _____

Voucher only available to clients who live or work in Doncaster or Rotherham and are valid for 28 days from the date of issue.

For Pharmacist To Complete

