

This Patient Group Direction (PGD) must only be used by registered community pharmacists who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

## **Patient Group Direction**

for the supply of

### **Varenicline 0.5mg and 1mg tablets**

by registered community pharmacists for

**smoking cessation in combination with motivational  
support**

**Public Health Dorset**

Version number: 2



Version Number: 2  
Review date: April 2018

Valid from: October 2016  
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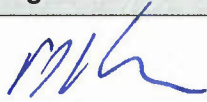
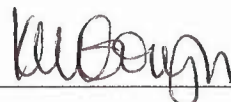
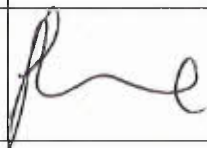
**CHANGE HISTORY**

Version number	Change details	Date
1	Original version adopted	March 2014
2	Routine review and update as version 1 expires 30 <sup>th</sup> Sept 2016	October 2016

**PGD DEVELOPMENT**

Name	Job title and organisation	Signature	Date
Christopher Ricketts	Head of Programmes, Public Health Dorset, Dorset County Council		26/9/16
Claire Rossiter	(pharmacist) Local Pharmaceutical Committee		6/10/16
Hayley Braid	Medicines Management Team, Dorset CCG		
<b>Other members of the PGD working group</b>			

**PGD AUTHORISATION**

Name	Job title and organisation	Signature	Date
<b>Senior doctor</b> Dr Paul Mason	Prescribing Lead, Dorset CCG		28/9/16
<b>Senior pharmacist</b> Katherine Gough	Head Of Medicines Management, Dorset CCG		28/9/16
Senior representative of professional group using the PGD	N/A		
Person signing on behalf of authorising body	Dr Jane Horne Consultant in Public Health, Dorset County Council		5/10/16

**PGD ADOPTION BY THE PROVIDER**

Name	Job title and organisation	Signature	Date
<b>Lead Pharmacist</b>			

**TRAINING AND COMPETENCY OF REGISTERED COMMUNITY PHARMACISTS WORKING UNDER THE PGD**

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	<b>Requirements of registered community pharmacists working under the PGD</b>
Qualifications and professional registration	Registered Pharmacist
Initial training	<ul style="list-style-type: none"> <li>• Before offering this service, all Pharmacists authorising treatment under this PGD must complete the NHS Centre for Smoking Cessation and Training (NCSCT) training and Initial training assessment online at <a href="http://www.ncsct.co.uk">www.ncsct.co.uk</a></li> <li>• Attend local training on smoking cessation, see Public Health Dorset Website for details <a href="http://www.publichealthdorset.org.uk">www.publichealthdorset.org.uk</a></li> </ul>
Competency assessment	<ul style="list-style-type: none"> <li>• Complete the varenicline training workbook and online questionnaire and declaration. This can be found on the Public Health Dorset Website.</li> <li>• Able to demonstrate competency in line with the NICE Good Practice Guidance: Patient group directions: competency framework for health professionals using patient group directions</li> </ul>
Ongoing training and competency	<ul style="list-style-type: none"> <li>• Attendance at local update training on smoking, see Public Health Dorset Website for details <a href="http://www.publichealthdorset.org.uk">www.publichealthdorset.org.uk</a></li> <li>• The pharmacy must have a copy of the Current BNF available for reference and be familiar with the information in the BNF about the use of varenicline.</li> </ul>
Lines of accountability	<ul style="list-style-type: none"> <li>• A registered pharmacist is accountable for his or her actions in accordance with the General Pharmaceutical Council. All registered pharmacists are personally accountable for their practice and in the exercise of professional accountability there is a requirement to maintain and improve their professional knowledge and competence.</li> <li>• The PGD may be used only within the confines of the service specification by pharmacists and pharmacies commissioned by PH Dorset</li> </ul>
<p><b>Characteristics of pharmacists <u>making repeat supplies</u> of varenicline:</b></p> <p>Ideally the pharmacist who is smokestop trained and makes the initial decision to supply varenicline will be involved in supporting the patient and making repeat supplies. However if that pharmacist is absent from the pharmacy on the day that the patient requires a repeat supply, the supply may be made by the pharmacist on duty. This is based on the principle that the PGD allows for 12 weeks supply and the initiating pharmacist has authorised that quantity to be supplied in 2 week quantities.</p>	

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## CLINICAL CONDITION

<b>Clinical condition or situation to which this PGD applies</b>	<p>As an adjunct to smoking cessation in combination with motivational support in nicotine-dependent adults.</p>
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>• Nicotine dependent adults identified as sufficiently motivated to quit. These people must be willing and able to attend structured stop-smoking counselling as part of the pharmacy 1:1 SmokeStop service.</li> <li>• 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.</li> </ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Patients under 18 years of age.</li> <li>• Women who are pregnant, planning a pregnancy, or who are breastfeeding</li> <li>• Smokers not sufficiently motivated to quit and those not willing to attend check-ups</li> <li>• If a smoker's attempt to quit is unsuccessful using NRT, varenicline or bupropion, do not offer varenicline within six months unless special circumstances have hampered the person's initial attempt to stop smoking, when it may be reasonable to try again sooner.</li> <li>• Patients who have previously had a hypersensitivity reaction to a medicine that involved angioedema</li> <li>• Patients who have previously had Stevens-Johnson Syndrome or Erythema Multiforme</li> <li>• Any renal impairment</li> <li>• Hypersensitivity to varenicline or any of its excipients</li> <li>• Epilepsy or history of seizures (lowering of seizure threshold has been reported)</li> <li>• Patients already using NRT</li> <li>• Patients not recommended to use varenicline by their GP</li> </ul>
<b>Cautions (including any relevant action to be taken)</b>	<p>Physiological changes resulting from smoking cessation, with or without treatment with varenicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin).</p> <p>Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in patients attempting to quit smoking with or without treatment. If serious neuropsychiatric symptoms occur whilst on varenicline treatment, patients should discontinue varenicline immediately and contact a healthcare professional for re-evaluation of treatment.</p> <p>Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly and referred to their GP.</p>

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	<p>Patients taking varenicline 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.</p>
<p><b>Arrangements for referral for medical advice</b></p>	<p>If the patient is excluded from receiving varenicline by the PGD exclusions listed above or if there are concerns about the cautions above, then they should be offered alternative smoking cessation products and advice. If the patient still wishes to obtain varenicline then they should be referred to their GP for a consultation in which the GP can make an assessment as to whether the benefits of prescribing would outweigh the risks.</p>
<p><b>Action to be taken if patient excluded</b></p>	<ul style="list-style-type: none"> <li>• <b>Do not supply varenicline under PGD.</b></li> <li>• Referral to GP</li> <li>• Pharmacist may recommend alternative e.g. NRT</li> </ul>
<p><b>Action to be taken if patient declines treatment</b></p>	<p>As above</p>
<p><b>Interactions</b></p>	<p>In clients with severe renal impairment, the concomitant use of cimetidine and varenicline should be avoided.</p> <p>There have been post marketing reports of increased intoxicating effects of alcohol in patients treated with varenicline.</p> <p>Safety and efficacy of varenicline in combination with other smoking cessation therapies have not been studied and is not recommended.</p>

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## DETAILS OF THE MEDICINE

<b>Name, form and strength of medicine</b>	Varenicline (Champix®) Tablets, 0.5mg or 1mg
<b>Legal category</b>	Prescription Only Medicine
<b>Indicate any <u>off-label use</u> (if relevant)</b>	<i>Not relevant</i>
<b>Route/method of administration</b>	<ul style="list-style-type: none"> <li>• Oral</li> <li>• Varenicline tablets should be swallowed whole with water, and can be taken with or without food</li> <li>• Nausea may be reduced if taken with or after food.</li> </ul>
<b>Dose and frequency</b>	<p>Patients should set a quit date to stop smoking, varenicline treatment should usually start 1-2 weeks before this date.</p> <p>The recommended dose is 1 mg oral varenicline twice daily with a 1-week titration at the beginning and end of the 12 week period.</p> <p><b>Days 1-3:</b> 0.5mg (white) once daily</p> <p><b>Days 4-7:</b> 0.5mg (white) twice daily</p> <p><b>Day 8 onwards:</b> 1mg (blue) twice daily</p> <p><b>End of treatment reduction (titration pack in reverse)</b></p> <p>1mg (blue) twice daily for 7 days then 0.5mg (white) twice daily for 4 days then 0.5mg daily for 3 days</p> <ul style="list-style-type: none"> <li>• Provision for the first two weeks supply is provided as a titration pack, which contains one clear blister of 11 x 0.5 mg film-coated tablets and a second clear blister of 14 x 1 mg film-coated tablets.</li> <li>• From this point, maintenance packs are supplied for 2 weeks at a time.</li> <li>• For the final two weeks a titration pack should be provided to be used in reverse.</li> <li>• Patients who cannot tolerate side effects, but are still motivated to continue treatment may have their dose lowered temporarily or permanently to 0.5mg twice daily. For patients taking this dose, titration for the last week by taking 0.5mg daily is recommended.</li> </ul>
<b>Quantity to be administered and/or supplied</b>	<p>12 weeks supply of varenicline.</p> <p>(Two weeks supply at a time in line with the requirements of the pharmacy SmokeStop service specification)</p>
<b>Maximum or minimum</b>	Maximum 12 weeks supply of varenicline.

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treatment period																													
<b>Adverse effects</b>	<p><b>Very common (<math>\geq 1/10</math>)</b></p> <table border="1"> <tr><td>• Nasopharyngitis</td></tr> <tr><td>• Insomnia</td></tr> <tr><td>• Abnormal dreams</td></tr> <tr><td>• Headache</td></tr> <tr><td>• Myalgia</td></tr> <tr><td>• Chest pain,</td></tr> <tr><td>• Nausea</td></tr> </table>	• Nasopharyngitis	• Insomnia	• Abnormal dreams	• Headache	• Myalgia	• Chest pain,	• Nausea																					
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	<p><b>Common (<math>\geq 1/100</math> to <math>&lt;1/10</math>)</b></p> <table border="1"> <tr><td>• Bronchitis</td><td>• Sinusitis</td></tr> <tr><td>• Weight increased</td><td>• Increased appetite</td></tr> <tr><td>• Decreased appetite</td><td>• Vomiting</td></tr> <tr><td>• Diarrhoea</td><td>• Gastro oesophageal reflux disease</td></tr> <tr><td>• Abdominal pain</td><td>• Constipation</td></tr> <tr><td>• Dyspepsia</td><td>• Abdominal distension</td></tr> <tr><td>• Flatulence</td><td>• Toothache</td></tr> <tr><td>• Somnolence</td><td>• Dry mouth</td></tr> <tr><td>• Dysgeusia</td><td>• Dizziness</td></tr> <tr><td>• Dyspnoea</td><td>• Cough</td></tr> <tr><td>• Back pain</td><td>• Arthralgia</td></tr> <tr><td>• Liver function test abnormal</td><td>• Fatigue</td></tr> <tr><td>• Pruritus*</td><td></td></tr> <tr><td>• Rash*</td><td></td></tr> </table>	• Bronchitis	• Sinusitis	• Weight increased	• Increased appetite	• Decreased appetite	• Vomiting	• Diarrhoea	• Gastro oesophageal reflux disease	• Abdominal pain	• Constipation	• Dyspepsia	• Abdominal distension	• Flatulence	• Toothache	• Somnolence	• Dry mouth	• Dysgeusia	• Dizziness	• Dyspnoea	• Cough	• Back pain	• Arthralgia	• Liver function test abnormal	• Fatigue	• Pruritus*		• Rash*	
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<p><b>*Severe cutaneous reactions, including Stevens Johnson Syndrome, Erythema Multiforme and angioedema have been reported, therefore patients should discontinue treatment with varenicline at the first sign of rash or skin reaction and report this side effect to their GP or pharmacist immediately</b></p>																													
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	<p>For a full list of adverse effects, please refer to the BNF or the summary of product characteristics.</p> <p>Report all serious suspected adverse reactions to the MHRA via the <a href="#">Yellow Card system</a> (even if they are listed in the BNF or above). Serious reactions are those which are fatal, life threatening, disabling, incapacitating or which result in prolonged hospitalisation and/or are medically significant.</p>
<b>Records to be kept</b>	<p>Records of the consultation must be uploaded onto PharmOutcomes using the template specified by Public Health Dorset. This information automatically prompts payment as well as acting as a record which can be referred to later on. Anonymised, data from PharmOutcomes is shared with the commissioner for monitoring and audit purposes only.</p> <p>In addition:</p> <ul style="list-style-type: none"> <li>• The pharmacy must make a record of the supply on the patient medication record (PMR).</li> <li>• The person's GP must be informed via fax</li> </ul>
<b>Follow-up advice to be given to patient or carer</b>	<p>Clients can benefit from additional lifestyle advice and support from LiveWell Dorset <a href="http://www.livewelldorset.co.uk">www.livewelldorset.co.uk</a> 0800 8401628 / 01305 233105</p>

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## PATIENT INFORMATION

### Written information to be given to patient or carer

- Clients must be informed that information relating to the supply of varenicline under PGD will be passed on to their GP and the SmokeStop Service to ensure proper record keeping and client safety.
- Advice to clients should include specific advice on dosage, duration of treatment, and side effects.
- All suspected side effects should be reported to the MHRA via the [Yellow Card system](#).
- Clients should be advised to **discontinue treatment** and seek prompt medical advice if they, or their family or carers notice that the patient has developed increased anxiety, depression, aggression, irrational behaviour, psychosis or suicidal ideation.
- Severe cutaneous reactions, including Stevens Johnson Syndrome, Erythema Multiforme and angioedema have been reported, therefore patients should **discontinue treatment** with varenicline at the first sign of rash or skin reaction and report this side effect to their GP or pharmacist immediately
- Clients should be advised on obtaining further supplies of varenicline and the need to attend at 2 weekly intervals.
- 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.
- General smoking cessation advice should also be given, particularly with regard to:
  - Withdrawal symptoms
  - Possible changes in the body on stopping smoking, e.g. weight gain

Clients wanting more information can be referred to:  
Live Well Dorset: 0800 8401628

## APPENDICES

### Appendix A: Key references

1. Summary of Product Characteristics for varenicline (Champix®), accessed via: <http://www.medicines.org.uk/emc/medicine/19045> (last updated 03/08/16)
2. The current edition of the BNF ([www.bnf.org](http://www.bnf.org))
3. NHS Executive HSC 2000/026. Client Group Directions (England Only), London 2000.

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**Appendix B Health professionals' agreement to practise**

**Patient Group Direction for the Supply and/or Administration of varenicline (Champix®)**

This Patient Group Direction is for use in

.....Pharmacy

Or by a locum pharmacist in pharmacies approved to offer the service

The direction must be read, agreed to and signed by each of the pharmacists who work within it. All professions must act within their appropriate Code of Professional Conduct. One copy should be given to each pharmacist with the master copy being kept by the manager of each pharmacy approved to offer the service.

***I confirm that I have read and understood the content of this Patient Group Direction and that I have received the appropriate training in order to implement it effectively. I agree to work within its parameters.***

Name of community pharmacist	Signature	Date

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