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PATIENT GROUP DIRECTION (PGD)

For the Supply of
Varenicline (Champix ®)

Version:	1.3
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SOMERSET

PATIENT GROUP DIRECTION (PGD) FOR: **THE SUPPLY OF VARENICLINE (CHAMPIX ®)**

VERSION CONTROL

Document Status:	
Version:	1.3

Document Change History		
Version	**Date**	**Comments**
1.1	11 June 2015	Signature sheet amended, return a copy to Solutions4Health
1.2	July 2015	Updating signature sheets
1.3	March 2017	Changed all references to Solutions4Health to Somerset County Council

Author	Nicola Crocker
Document reference	

PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF VARENICLINE (CHAMPIX ®)

Drug: Varenicline 500microgram tablets and 1mg tablets
Condition: Patients accessing Stop Smoking Services in need of pharmacological treatment
Professional Group: Pharmacists

You must be Authorised by Name, Under the Current Version of this PGD before you attempt to work according to it

Clinical Condition		
1.	**Define condition / indication**	Patients accessing Stop Smoking Services in need of pharmacological treatment.
2.	**Inclusion criteria**	• Clients receiving group or individual advice and support from smoking cessation services either provided directly by Smokefreelife Somerset, or by Community Pharmacies approved to provide smoking cessation services by Somerset County Council • Tobacco users aged 18 years and above who are sufficiently motivated to quit • Clients willing to work with a Stop Smoking Advisor towards setting a quit date and returning for support • Clients who have had unsuccessful quit attempts in the past may be considered for treatment under this PGD, regardless of the time since their last quit attempt • A full medical history is taken and documented and there are no contraindications to treatment with varenicline and any cautions to use have been considered and recorded (see Criteria for Exclusion and Referral)

3.	**Exclusion criteria**	• Pregnancy • End stage renal disease • Renal impairment • Epilepsy • Patients with a current diagnosis or previous history of psychiatric illness/symptoms such as schizophrenia, bipolar disorder and major depressive disorder, - including any psychiatric condition requiring medication or psychotherapy in past 5 years and clients should be monitored closely and advised accordingly. Refer to BNF, under varenicline section, in particular the MHRA / CHM advice • Hypersensitivity to varenicline or any of the ingredients in the product • Child under 18 years old • Client not sufficiently motivated to quit • Varenicline should not be used with other pharmacotherapies for smoking cessation, i.e. bupropion and nicotine replacement therapies

4.	**Cautions / Need for further advice**	Pharmacist can discuss these cautions with clients, but they may wish to refer clients with the following conditions to their GP. **Effect of smoking cessation** 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). As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. **Patients on insulin** May be supplied with varenicline, but should be advised to monitor their blood glucose levels closely. **Neuropsychiatric symptoms** Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking with varenicline in the post-marketing experience. Not all patients had stopped smoking at the time of onset of symptoms and not all patients had known pre-existing psychiatric illness.

4.	**Cautions / Need for further advice cont.,**	Clinicians should be aware of the possible emergence of significant depressive symptomatology in patients undergoing a smoking cessation attempt, and should advise patients accordingly. Varenicline should be discontinued immediately if agitation, depressed mood or changes in behaviour or thinking that are of concern for the doctor, the patient, family or caregivers are observed, or if the patient develops suicidal ideation or suicidal behaviour. In many post-marketing cases, resolution of symptoms after discontinuation of varenicline was reported although in some cases the symptoms persisted; therefore, ongoing follow up should be provided until symptoms resolve. Refer to BNF, under varenicline section, in particular the MHRA / CHM advice. **Cardiovascular events** In a trial of patients with stable cardiovascular disease (CVD) certain cardiovascular events were reported more frequently in patients treated with varenicline. A meta-analysis of 15 clinical trials, which included the smoking cessation trial of patients with stable CVD, had similar results. 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.

4.	**Cautions / Need for further advice cont.,**	**Seizures** In clinical trials and post-marketing experience there have been reports of seizures in patients with or without a history of seizures, treated with varenicline. It should be used cautiously in patients with a history of seizures or other conditions that potentially lower the seizure threshold. **Breast-feeding** It is unknown whether varenicline is excreted in human breast milk. Animal studies suggest that varenicline is excreted in breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with varenicline should be made taking into account the benefit of breast-feedingto the child and the benefit of varenicline therapy to the woman. **Drug interactions** It should be noted that the metabolism of some drugs will be affected if a patient stops smoking, as cigarette smoke interacts with some medicines by stimulating the cytochrome P450 enzymes (particularly CYP1A2). The drugs in which the interaction is of clinical importance are: warfarin, theophylline, cinacalcet, ropinirole, methadone, insulin, and some antipsychotics including chlorpromazine, clozapine, and olanzapine. Patients should be asked to refer to their GP for appropriate medication review before stopping smoking. For a full list of interactions refer to the appropriate reference sources, including UKMI Q&A 136.4, and the BNF. Varenicline should not be used with other pharmacotherapies for smoking cessation, i.e. bupropion and nicotine replacements therapies.
5.	**Action if excluded**	Discuss alternative products if suitable i.e. Nicotine Replacement Therapies or bupropion. An initial supply of two weeks of NRT can be supplied by the Pharmacist. The subsequent supplies of NRT may be issued by the Pharmacist if they are a trained Stop Smoking Advisor and are providing the behavioural support, or alternatively refer back to Somerset County Council for the direct supply of these products. For bupropion refer the client to their GP.

6.	**Action if patient declines or is excluded**	Refer the client to their GP for further assessment and advice.
7.	**When further Medical Advice should be sought**	**Cutaneous reactions** There have also been post-marketing reports of rare but severe cutaneous reactions, including Stevens-Johnson Syndrome and Erythema Multiforme in patients using varenicline. As these skin reactions can be life threatening, patients should discontinue treatment at the first sign of rash or skin reaction and contact a healthcare provider immediately.

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8.	Drug Details	
	Name, form and strength of medicine	Varenicline 500microgram tablets and 1mg tablets
	Legal Category	Prescription Only Medicine (POM)
	Black Triangle Status	Yes – NICE guidance (July 2007) supports the use of varenicline (Champix ®) in those who have expressed a wish to stop smoking
	Route / method of administration	Oral
	Dosage	Days 1 – 3 : 500micrograms once a day Days 4 – 7 : 500micrograms twice a day Day 8 to end of treatment (up to 12 weeks in total) : 1mg twice a day Maximum single dose 1mg, maximum daily dose 2mg The client should set a date to stop smoking. Varenicline dosing should usually start 1 – 2 weeks before this date. Clients who are not willing or able to set the target quit date within 1 – 2 weeks, can be offered to start treatment, and then choose their own quit date within 5 weeks. Patients who cannot tolerate adverse reactions to varenicline may temporarily or permanently reduce their dose to 500 micrograms twice daily. Days 1 – 3 : 500micrograms once a day Days 4 to end of treatment : 1mg once a day Risk of relapse, irritability, depression and insomnia on discontinuation (consider dose tapering on completion of 12 week course).
	Frequency	Treatment to be provided every two weeks.

	Duration of treatment	Normally a maximum 12 weeks supply for any one quit attempt. However in exceptional circumstances where the client has successfully stopped smoking towards the end of 12 weeks, a further supply (maximum 12 weeks) can be supplied after discussion with the Pharmacist or Stop Smoking Advisor.
	Total dose number to supply / administer	Session 1 – 1x starter pack (25 tablets) Session 2 – 1 x 28 1mg tablets Session 3 – 1 x 28 1mg tablets Session 4 – 1 x 28 1mg tablets Session 5 – 1 x 28 1mg tablets Session 6 – 1 x 28 1mg tablets
9.	**Side effects**	Smoking cessation with or without treatment is associated with various symptoms. For example: Irritability Dysphoric or depressed mood Frustration or anger Anxiety Restlessness Difficulty concentrating Increased appetite or weight gain Insomnia Decreased heart rate In clinical trials, in general, when adverse reactions occurred, onset was in the first week of therapy; and severity was generally mild to moderate. In clients treated with the recommended dose of 1mg twice a day following the initial titration period the adverse event most commonly reported was nausea (28.6%). In the majority of cases nausea occurred early in the treatment period, was mild to moderate in severity and seldom resulted in discontinuation.

9.	**Side effects cont.,**	If nausea is a problem for the patient their dose can be reduced to 500micrograms twice a day. **Very common side effects (≥ 1 in 10),** • Abnormal dreams, insomnia • Headache • Nausea • Nasopharyngitis **Common side effects (≥ 1 in 100 to <1 in 10)** • Weight increased, decreased appetite, increased appetite • Somnolence, dizziness, dysgeusia • Gastroesophageal reflux disease, vomiting, constipation, diarrhoea, abdominal distension, abdominal pain, toothache, dyspepsia, flatulence, dry mouth • Chest pain, fatigue • Bronchitis, sinusitis • Dyspnoea, cough • Rash, pruritus • Arthralgia, myalgia, back pain • Liver function test abnormal Refer to Appendix One for uncommon and rare side effects.
10.	**Reporting procedure of Adverse Reactions**	As varenicline is a 'black triangle' drug, it is under intense surveillance by the CHM and MHRA and so all adverse and suspected adverse reactions should be reported using the 'Yellow Card' reporting system, AND be reported to Somerset County Council Public Health. Nurses, pharmacists and the public can report adverse reactions to the CHM. This can be done by using a hard copy of a "Yellow Card" (available in the back of the BNF) or on-line via the website https://yellowcard.mhra.gov.uk/

11.	**Advice to patient / carer**	• Tablets should be swallowed whole with water and can be taken with or without food. • Where the patient is experiencing nausea they should be advised to take the tablets with a large glass of water after food. • The manufacturer's patient information leaflet (PIL) must be given to the client. • Varenicline may have minor or moderate influence on the ability to drive and use machines. Varenicline may cause dizziness and somnolence and therefore may influence the ability to drive and use machines. Clients should be advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether varenicline affects their ability to perform these activities. • Advise clients of possible side effects of smoking cessation and varenicline therapy. • Clients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts. • Clients 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 a heart attack (myocardial infarction). • At the end of treatment, discontinuation of varenicline is associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients. The client should be advised of this, and the Stop Smoking Advisor should discuss or consider the need for dose tapering. • There have been post-marketing reports of hypersensitivity reactions including angioedema in patients treated with varenicline. Clinical signs included swelling of the face, mouth (tongue, lips, and gums), neck (throat and larynx) and extremities. There were rare reports of life-threatening angioedema requiring urgent medical attention due to respiratory compromise. Patients experiencing these symptoms should discontinue treatment with varenicline and contact a health care provider immediately.

12.	**Arrangements for follow up**	Client should be followed up at fortnightly intervals for the duration of their treatment.

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Referral Arrangements and Audit Trail		
13.	**Referral arrangements**	• Pharmacists should refer clients who are excluded from the PGD to their GP • The client will be referred to their GP if the Pharmacist thinks that treatment with bupropion might be more appropriate • The Pharmacist can supply the first two weeks of NRT, but the client should be referred back to Somerset County Council for direct supply of the remainder of the treatment if the Pharmacist is not a trained Stop Smoking Advisor

14.	**Record specific information for the supply/administration of medicines to include details for audit trail and significant events**	• Patient's name, address, date of birth and GP details; • Date supplied and name of the Clinician who supplied the medication; • Batch number and expiry date; • 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. Following the last consultation, the Record of Supply Form and the original Client Assessment Form must be kept in the pharmacy for at least two years. All patient details should be recorded on the PharmOutcomes database.

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Staff Characteristics	
Professional qualifications	A pharmacist currently registered with the General Pharmaceutical Council.
Specialist competencies or qualifications	Training on the operation of this PGD by or on behalf of Somerset County Council (Smokefreelife Somerset).
Continued education & training	Pharmacist will maintain clinical knowledge appropriate to their practice as part of their Continuing Professional Development.
Additional Requirements	If the Pharmacist is also providing the behavioural support to the client, they should be a trained Stop Smoking Advisor, and on the National Centre for Smoking Cessation and Training (NCSCT) certified practitioner list.

References / Resources and comments

British National Formulary (BNF) No. 69 (March 2015)

Medicines and Health Product Regulatory Agency (MHRA) Safety Alerts: November 2008 and subsequent updates.

https://www.gov.uk/drug-safety-update

National Institute for Health and Clinical Excellence (NICE)

- Varenicline for smoking cessation. NICE technology appraisal guidance (TA 123), July 2007
- Smoking cessation services. NICE Public Health Guidance 10. Last updated November 2013

Summary of Product Characteristics for Champix® updated 18 December 2014. Pfizer Limited.

https://www.medicines.org.uk/emc/medicine/19045

UK Medicines Information (UKMI) bulletin Q&A 136.4: Which medicines need dose adjustment when a patient stops smoking? August 2012.

The following PGDs were read as part of the development of this PGD:

Patient Group Direction (PGD) for the Supply of Varenicline▼ (Champix®) by Authorised PGD Accredited Community Pharmacists working in Berkshire, 2014 – 2015. Bracknell Forest Council.

Patient Group Direction for the Supply of Varenicline▼ (Champix®) by Smoking Cessation Advisers. Bromley Healthcare.

Patient Group Direction (PGD) for the Supply of Varenicline by Community Pharmacists. 6th March 2014. North Somerset Council and North Somerset CCG.

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This patient group direction must be agreed to and signed by all health care professionals involved in its use. Somerset County Council should hold the original signed copy. The PGD must be easily accessible in the clinical setting	
Organisation	

Authorisation	**Signature** **Date**
Nominated GP	Andrew Tresidder 19/04/2017 DR. ANDREW TRESIDDER GP. GMC 2823735
Director of Public Health	19/04/2017 **Trudi Grant, MSc PH, UKPHR, FFPH** **Director of Public Health** Somerset County Council
Senior Pharmaceutical Advisor	19/04/2017 REBECCA MYERS 2049387
Consultant Microbiologist **(for Antibiotics)**	

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Individual Authorisation

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 Managers: 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 and agree to supply / administer this medicine only in accordance with this PGD.

Location:				
Name of Professional	**Professional registration no. (pharmacists only**	**Signature**	**Authorising Manager[1]**	**Date**

Please ensure a copy of this page is kept by the Line Manager.

Pharmacists - Please return a copy to: Smokefreelife Somerset, Public Health Department, Somerset County Council, PP B3S 2, County Hall, Taunton, TA1 4DY.

Appendix One – Uncommon and rare side effects

System Organ Class	Adverse Drug Reactions
Infections and infestations	
Uncommon	Fungal infection, viral infection
Blood and lymphatic system disorders	
Rare	Platelet count decreased
Metabolism and nutrition disorders	
Rare	Polydipsia
Not Known	Diabetes mellitus, hyperglycaemia
Psychiatric disorders	
Uncommon	Panic reaction, thinking abnormal, restlessness, mood swings, depression*, anxiety*, hallucinations*, libido increased, libido decreased
Rare	Dysphoria, bradyphrenia
Not Known	Suicidal ideation, psychosis, aggression, abnormal behaviour, somnambulism
Nervous system disorders	
Uncommon	Seizure, tremor, lethargy, hypoaesthesia
Rare	Cerebrovascular accident, hypertonia, dysarthria, coordination abnormal, hypogeusia, circadian rhythm sleep disorder
Eye disorders	
Uncommon	Conjunctivitis, eye pain
Rare	Scotoma, scleral discolouration, mydriasis, photophobia, myopia, lacrimation increased
Ear and labyrinth disorders	
Uncommon	Tinnitus
Cardiac disorders	
Uncommon	Angina pectoris, tachycardia, palpitations, heart rate
Rare	Atrial fibrillation, electrocardiogram ST segment depression, electrocardiogram T wave amplitude decreased
Not Known	Myocardial infarction
Vascular disorders	
Uncommon	Blood pressure increased, hot flush

Respiratory, thoracic and mediastinal disorders	
Uncommon	Upper respiratory tract inflammation, respiratory tract congestion, dysphonia, rhinitis allergic, throat irritation, sinus congestion, upper- airway cough syndrome, rhinorrhoea
Rare	Laryngeal pain, snoring
Gastrointestinal disorders	
Uncommon	Haematochezia, gastritis, change of bowel habit, eructation, aphthous stomatitis, gingival pain
Rare	Haematemesis, abnormal faeces, tongue coated
Skin and subcutaneous tissue disorders	
Uncommon	Erythema, acne, hyperhidrosis, night sweats
Not Known	Severe cutaneous reactions, including Stevens Johnson Syndrome and Erythema Multiforme, angioedema
Musculoskeletal and connective tissue disorders	
Uncommon	Muscle spasms, musculoskeletal chest pain
Rare	Joint stiffness, costochondritis
Renal and urinary disorders	
Uncommon	Pollakiuria, nocturia
Rare	Glycosuria, polyuria
Reproductive system and breast disorders	
Uncommon	Menorrhagia
Rare	Vaginal discharge, sexual dysfunction
General disorders and administration site conditions	
Uncommon	Chest discomfort, influenza like illness, pyrexia, asthenia,
Rare	Feeling cold, cyst
Investigations	
Rare	Semen analysis abnormal, C-reactive protein increased, blood calcium decreased
* Frequencies are estimated from a post-marketing, observational cohort study	