NHS
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PATIENT GROUP DIRECTION

Name of Medicine :	Varenicline (Champix®) Tablets
Legal Classification :	Prescription only Medicine
PGD Ref No :	NPGD 20 012
Replacing PGD Ref No :	NPGD 18 012

Effective Date :	1st May 2020
Review Date :	1st May 2022

Professional Group authorised to use PGD on completion and submission of an Approved Practitioner Form:	Community Pharmacists registered with the General Pharmaceutical Council working in NHS Ayrshire and Arran

PGD prepared/reviewed* by : (*delete as appropriate)			
	Doctor	**Pharmacist**	**Other**
Name	**John Freestone**	**Allan Wilson**	
Signature	J Freestone	Allan Wilson	
Date	**1/4/2020**	**1/4/2020**	

Approved on behalf of NHS Ayrshire & Arran
Chair or vice chair PGD group:
Name: Chris Rodden
Signature: C Rodden
Date: 1/4/2020

Description of Treatment	
Name of medicine : Varenicline (Champix®) Tablets	
POM/P/GSL :	**POM** Prescription only medicine
Pharmaceutical Form :	Tablets
Strength :	0.5mg and 1mg
Clinical situation for use of this PGD	Clients accessing the pharmacy smoking cessation service who are motivated to stop smoking and are assessed as suitable for varenicline
Inclusion criteria	• Clients 18 years of age and over • Dependent smoker (i.e. they smoke within 30minutes of waking up and /or find quitting unaided difficult) identified as sufficiently motivated to quit • The client agrees to receive ***behavioural support*** according to the agreed protocol • Completion of Varenicline Clinical Risk Assessment Form and the pharmacist is able to supply varenicline
Exclusion criteria	• Client under 18 years of age • Smokers not sufficiently motivated to quit • Pregnant or breastfeeding women • Sensitivity to varenicline or any of its excipients • Known renal impairment • Epilepsy • Clients using other smoking cessation therapies e.g. NRT, e-cigarette • Completion of Varenicline Clinical Risk Assessment Form and pharmacist is unable to supply varenicline • Client taking clozapine
Dosage :	**Days 1 - 3:** 500 mcg (white tablets) once daily **Days 4 – 7:** 500 mcg tablets twice daily **Day 8 to the end of the treatment:** 1mg (blue tablets) twice daily for 11 weeks. (Reduce to 0.5mg twice daily if not tolerated) Maximum single dose 1mg

	Maximum daily dose 2mg Client should set a date to stop smoking. Client should 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 Clients who cannot tolerate the adverse effects of varenicline may be offered NRT
Total Dosage:	11x 0.5mg and 154x 1mg tablets (Maximum dose)
Route of Administration :	Oral
Frequency of Administration :	**1st consultation (Assessment)** Client should set a quit date between the next 8-14 days. Supply 14 day starter pack (11 x 0.5mg tabs with 14 X 1mg tablets) Clients should attend the pharmacy each week for support Set a formal quit date between one and two weeks after starting varenicline Take a carbon monoxide reading **2nd consultation (before quit date)** Confirm quit date. Monitor carbon monoxide reading. **3rd consultation** Monitor carbon monoxide reading and confirm abstinence. Supply varenicline tablets 1mg twice a day for 2 weeks (or lower dose if unable to tolerate side effects) ***Subsequent consultations*** Supply varenicline tablets if client has stopped smoking and carbon monoxide reading confirms abstinence. ***Final consultation (week 10 – 12)*** Discuss coping strategies when the support service finished. Supply varenicline tablets if client has stopped smoking and carbon monoxide reading confirms

	abstinence.
Duration of Treatment :	12 weeks
Total Treatment Quantity :	11x 0.5mg and 154x 1mg tablets
Action if patient is excluded from treatment under this PGD	Pharmacists should offer dual therapy NRT when supply through pharmacy is not permitted within the exclusion criteria
Interactions	No clinical meaningful drug interactions have been reported. Since metabolism of varenicline represents less than 10% of its clearance, active substances known to affect the cytochrome P450 system are unlikely to alter the pharmacokinetics of varenicline and therefore a dose adjustment of varenicline would not be required.
Adverse Effects	• Nausea • Sleep disorders/ abnormal dreams • Headache • Appetite changes • Dry mouth /taste disturbances • Drowsiness • Dizziness For less common side effects please refer to BNF
Follow-up treatment	Discontinue treatment at end of 12 week course
Written/Verbal Advice to be given to patient	• Advice to clients should include specific product advice on dosage, method of administration and side effects • If client experiences any extreme side effects they should seek medical advice - Varenicline should be discontinued immediately if agitation, depressed mood or changes in behaviour that are of concern for the pharmacist, clients family or caregiver are observed or if the client develops suicidal thoughts or suicidal behaviour • The major reasons for varenicline failure are: - Unrealistic expectations; - Lack of preparation for the fact that tablets may cause nausea; - Insufficient support from trained smoking cessation advisor/pharmacist/pharmacy support staff • It is important to make sure that the client understands the following points: 1. Varenicline is not a magic cure: effort and determination are crucial

	2. Varenicline works by acting on the parts of the brain which are affected by nicotine in cigarettes 3. Varenicline does not remove all the temptation to smoke, but it does make abstinence easier (it takes the edge of the discomfort by reducing the severity of tobacco withdrawal symptoms such as craving to smoke, irritability, poor concentration and low mood) 4. Clients may experience mild nausea usually about 30 minutes after taking it. This reaction often diminishes gradually over the first few weeks, and most clients tolerate it without problems; The following general advice should also be given: • Follow-up and obtaining further supplies • Possible changes in the body on stopping smoking e.g. weight gain • Effects on driving or using machinery • Clients on insulin should monitor blood glucose closely • Clients on warfarin or theophylline should be advised that dosage adjustment may be necessary and they should contact their prescriber if they stop smoking • 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 clients. The pharmacist should inform the client accordingly
Record required of Supply/Administration	• Clients name, address, contact telephone number, date of birth and GP details; • Date supplied & name of the pharmacist who supplied the medication; • Details of any adverse drug reaction and actions taken including documentation in the clients medical record via GP; • All adverse reactions should be reported using the 'Yellow Card' reporting system. **www.yellowcard.gov.uk** • The varenicline clinical risk assessment should be completed for each client and retained in the pharmacy for a minimum of 3 years.