

## PHARMACIST INFORMATION SHEET

### EAST RIDING OF YORKSHIRE VARENICLINE PGD SERVICE

- The pharmacist working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD. Failure to comply with the PGD could result in a criminal prosecution under the Medicines Act.
- It is the responsibility of each pharmacist to practice only within the bounds of their own competence and in accordance with the General Pharmaceutical Council Codes of Professional Conduct. Pharmacists are reminded that they are professionally accountable to the General Pharmaceutical Council, their employers and the law.
- The PGD must be signed by each pharmacist working under the PGD and a copy of the signature sheet must be retained in the pharmacy with the PGD
- The pharmacist working under the PGD must 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 continuing professional development
- The pharmacy must keep a comprehensive record of supply under the PGD via PharmOutcomes (including patient details and medication supply). Additionally all provisions of Varenicline must be recorded on the patients PMR
- All medication supplied must be labelled. The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicines, including those supplied under a PGD.
- A patient information leaflet should be provided to patients treated under a PGD.
- Patients who normally pay for their NHS Prescriptions, receiving medicines under the Varenicline PGD must pay one prescription charge for each supply of Varenicline made under the PGD. Patient's exempt from NHS prescription charges will not be charged.

#### FIRST SUPPLY of Varenicline via PGD

- The pharmacist will assess the need and suitability for a client to receive Varenicline, in line with the PGD and service specification. Inclusion and exclusion criteria detailed in the PGD and service specification will be applied during the provision of the service.
- A Client Assessment / Record Form for Varenicline must be completed for every client. (Available on PharmOutcomes) This is used to record that the client hasn't declared any past or current medical history which would exclude them from receiving Varenicline. The supply of treatment must be recorded on the pharmacy medication record (PMR)
- Consent to share information with the smoking cessation advisor/ GP/ Specialist/ Key worker must be discussed with the client. Consent must be recorded on the client assessment form on PharmOutcomes.
- Advice to patients as outlined in the PGD to include:
  - discuss possible side effects
  - when a client needs to immediately stop treatment
  - actions clients can take to manage side effects
  - possibility of withdrawal reaction
- The clients GP must be informed of the supply of Varenicline to their patient via the PharmOutcomes automatic GP notification mechanism

#### SUBSEQUENT PGD CONSULTATIONS for Varenicline via PGD

- At each subsequent supply of Varenicline the pharmacist accredited to work under the PGD must confirm the following directly with the client as part of a formal consultation:
  - The client wants to continue treatment.
  - The client is continuing to try and quit smoking
  - The client is receiving on-going smoking cessation support from the stop smoking counselling service
  - No contra-indication is brought to light or has developed.

- Client has not developed any signs of agitation, depressed mood, suicidal thoughts or other serious mood changes (client to be referred to GP for prompt medical advice)
- No side effects have emerged that could potentially impair the quit attempt
- The Varenicline treatment continues to be appropriate

## **REFERRAL**

- Clients excluded from the PGD criteria must be referred back to the smoking cessation adviser to consider NRT.
- Clients who develop any serious adverse effects, including any signs of agitation, depressed mood, suicidal thoughts or other serious mood changes must be referred to GP for prompt medical advice. The pharmacist should contact the patient's GP surgery and arrange an appointment for the client to see the GP.

## **INFORMATION AND ADVICE FOR CLIENTS**

Varenicline has no clinically meaningful drug interactions based on clinical experience to date however stopping smoking may alter the metabolism of some drugs which may necessitate dosage adjustment.

Drugs in which this interaction is of clinical importance are:

- Theophylline (most affected);
- Clozapine (most affected);
- Olanzapine (most affected);
- Warfarin (moderately affected);
- Methadone (moderately affected);
- Insulin (moderately affected);
- Some antipsychotics including chlorpromazine, (moderately affected);
- Cinacalcet and Ropinirole (moderately affected).

Patients taking these medications should be made aware of possible effects of stopping smoking on their regular medications and the need for more frequent monitoring:

- Clients taking Warfarin should contact their Anticoagulation clinic to inform about stopping smoking and to arrange an earlier/ more frequent INR test;
- Clients taking insulin should be informed to be alert for signs of hypoglycaemia and to test their blood glucose more frequently;
- Clients taking Theophylline should be advised to inform their GP within two weeks about stopping smoking. They should be advised to continue with their usual doses but be alert for signs of increased theophylline blood levels e.g. nausea/ palpitations and seek urgent medical advice if these occur.
- Patients should be advised to inform their GP, Key worker or Specialist of their smoking cessation and to discuss possible dose reduction of affected medications as soon as smoking ceases.

For a full list of interactions refer to appropriate reference sources, including UKMI Q&A 136.4, <http://www.health.nsw.gov.au/tobacco/Publications/tool-14-medication-intera.pdf>, BNF.

Patients should also be advised of the following:

**Altered reaction to alcohol:** patients may experience increased drunkenness, unusual or aggressive behavior, no memory of things.

**History of psychiatric illness/ psychiatric symptoms:** Care should be taken in patients with a previous history of psychiatric illness / psychiatric symptoms (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.

Pharmacists should be aware of the possible emergence of significant depressive symptoms in clients undergoing a smoking cessation attempt. Clients should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood of concern, or suicidal thoughts.

Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. In addition, smoking cessation, with or without pharmacotherapy, has been associated with exacerbation of underlying psychiatric illness (e.g. depression).

Cardiovascular symptoms: Patients should inform their GP of any new or worsening cardiovascular symptoms and seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.

Hypersensitivity reactions: If the patient experiences swelling of the face, mouth (tongue, lips, gums), neck (throat, larynx) or extremities, whilst taking Varenicline they should discontinue treatment and seek medical advice immediately.

#### Cutaneous reactions (rare)

If the patient develops a rash or skin reaction whilst taking Varenicline, they should discontinue treatment at the first sign and seek medical advice immediately.

It is important to make sure that the patient understands the following points:

- Varenicline is not a magic cure: effort and determination are crucial;
- It works by acting on the parts of the brain which are affected by nicotine in cigarettes;
- It does not remove all the temptation to smoke, but it does make abstinence easier (it takes the edge off the discomfort by reducing the severity of tobacco withdrawal symptoms);
- About a third of clients may experience mild nausea usually about 30 minutes after taking Varenicline. This reaction often diminishes gradually over the first few weeks, and most patients tolerate it without problems;
- If the patient is finding the side effects intolerable, they should seek advice from their Stop Smoking Adviser or Pharmacist;
- The importance of follow-up and how to obtain further supplies;
- Possible changes in the body on stopping smoking e.g. weight gain;
- Varenicline may cause drowsiness and dizziness. If affected the patient should be advised not to drive or operate machinery;
- If the patient forgets to take Varenicline, they should not take a double dose to make up for the one they missed. It is important they take it as soon as they remember but if it is almost time for the next dose, they should not take the tablet they have missed;
- 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 and discuss or consider the need for dose tapering.

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.

### **TRAINING REQUIREMENTS**

- All pharmacists providing the Varenicline PGD Service have a professional responsibility to develop, reinforce and update their knowledge and skills on a regular basis and should undertake the following training:
  - CPPE – PGD e-learning program
  - Consultation skills training
  - Knowledge of the Summary of Product Characteristics (SPC) for Varenicline
  - Knowledge and understanding of the East Riding of Yorkshire Varenicline Patient group direction
  - Knowledge and understanding of the East Riding of Yorkshire Varenicline Service specification
  - Attendance at a Varenicline Service training event or liaison with someone who has attended the launch event.