**Protocol for the direct supply of Nicotine Replacement Therapy (NRT) by Everyone Health Stop Smoking Practitioners in the London Borough of Waltham Forest**

**Rational for NRT:**

Over 95% of smokers are nicotine dependent and cannot go for a day, even if unwell, without smoking. They experience a range of symptoms known as Withdrawal Syndrome if deprived of nicotine and this often acts as a barrier when they decide that they wish to stop smoking. Nicotine Replacement Therapy (NRT) has been developed as a safer way for those trying to quit, it allows the absorption of the nicotine that they crave. NRT is well tolerated and delivered slowly and at lower levels so it cannot create new nicotine dependency. NRT reduces the desire to smoke and withdrawal cravings. It provides a coping behaviour and supports the smoker in a staged quit – giving them breathing space to deal with their smoking behaviours and beliefs. If used correctly, at high enough doses and for long enough, NRT will delay weight gain and reduce the risk of relapse. There are a range of products to suit the habitual preferences of smokers.

**Use of this protocol:**

Use of this protocol is only authorised by the Everyone Health Professional Lead for Smoking Cessation, Brigitte McCormack for Stop Smoking Practitioners who:

1. Have a current certificate of authorisation which is not expired.
2. Have attended training on this protocol in the last 12 months.
3. Are Registered Practitioners on the NCSCT Register

All authorised users of this protocol will be required to sign the document located in *Appendix A* to acknowledge that they have read this clinical protocol in full, have received appropriate training and updates and are competent to use it.

**Note:**

Nicotine Replacement Therapy may be given out at Point of care to patients. All storage and transportation of NRT must be in line with guidance document ‘Storage and Transportation of Point of Care medications’. All NRT distributed to patients must have Batch number and Expiry date recorded on iMPACT. The bar code must be crossed through with a biro and a medication sticker should be applied. The patients name should be recorded on the outer box. It should be given to the patient with a patient information leaflet and contact details of the service should be highlighted to the patient in case of adverse event.

Adverse events should be reported and managed using the adverse events protocol.

**Clinical Condition**

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| 1.1 | Define Situation / Condition | Treatment of nicotine dependence and relief of withdrawal symptoms associated with smoking cessation. The NRT will be supplied by trained stop smoking practitioners who will directly distribute NRT to clients who are being supported by the Everyone Health Waltham Forest Stop Smoking Service.  The decision to use NRT will be guided by NICE / DH guidance depending on:   * Client preference * Client’s previous experience of smoking cessation aids * Contraindications, cautions and the potential for adverse effects * The availability of smoking cessation counselling and support * The likelihood that the client will follow the course of treatment |
| 1.2 | Aim of Treatment of Care | To provide nicotine replacement products and behavioural support to clients with tobacco smoking dependence. Therefore providing relief of nicotine withdrawal symptoms, and aiding smoking cessation. |
| 1.3 | Criteria for Inclusion | Tobacco users who are motivated to quit smoking and meet the level 3 criteria.  The service is available to:   * Pregnant and breastfeeding women * Women planning a pregnancy in the next 12 months * Those with Long Term conditions * Those with mental health conditions * Those with learning disabilities * Those receiving treatment for substance misuse issues * Individuals over 12 years of age but under the age of 21 * Those smoking 40 or more cigarettes a day * Those who have tried to stop smoking more than three times in the last three years unsuccessfully * Those who have anyone living in their home who is either under school aged, or has a Long Term condition |
| 1.4 | Criteria for Exclusion | Individuals who do not meet the Level 3 inclusion criteria plus those who do but:   * Non-smokers or occasional smokers * Those not sufficiently motivated to quit or use NRT * Those already using NRT, Bupropion or Varenicline from another source * Individuals under 12 years of age * Those who are unable to consent to treatment * Clients who have experienced an acute cardio-vascular event in the last 4 weeks, i.e. myocardial infarction (heart attack), cerebral vascular accident (stroke) or heart surgery who have not had their NRT treatment initiated whilst they were in hospital or do not have a written recommendation from their consultant for NRT treatment. * Clients who have had a previous serious adverse reaction to NRT or any of the other ingredients contained in the products (e.g. glue in patch). * [Patches only] clients with a generalised skin disease such as psoriasis, chronic dermatitis, clients who have had a previous reaction to transdermal patches * [Nasal spray only] clients with chronic nasal disorders such as polyposis, vasomotor rhinitis and perennial rhinitis. * [QuickMist only] Patients undergoing treatment for alcohol dependency |
| 1.5 | Cautions when issuing direct supply of NRT | Supply with caution in patients with:   * Hypertension * Stable angina pectoris * Cerebrovascular disease * Occlusive peripheral arterial disease * Heart failure * Hyperthyroidism * Phaeochromocytoma * Diabetes mellitus * Renal or hepatic impairment * Peptic ulcer * Pregnant and breast feeding clients * Potential risks and benefits of nicotine should be carefully evaluated before use in clients taking anticonvulsant therapy or with a history of epilepsy, as cases of convulsions have been reported in association with nicotine   Please refer to *Appendix B* for a Medical Questionnaire Stop Smoking Practitioners are required to complete with clients for the Direct Supply of NRT under this Protocol.  For the above clients and with the client’s consent a cautions letter should be sent to their GP notifying them that NRT has been commenced. The letter needs to be copied and filed in the notes. *See Appendix C for letter template.* |
| 1.6 | Drug Interactions | Smoking cessation, with or without nicotine replacement therapy, may alter the effects of certain other medications (listed below) which may require dose adjustment.  Practitioners will undertake the health questionnaire (*Appendix B)* with each client, and identify any contraindication or cautions in the protocol and act accordingly. The risks associated with the use of NRT are substantially outweighed in virtually all circumstances by the well-established dangers of continuing smoking.  Any client who is taking any of the medications listed below a letter should be sent to their GP notifying them that NRT has been commenced (with the client’s consent). The letter needs to be copied and filed in the notes. *See Appendix C for letter template.*  Clients who are on the above medications will also need another letter to GP if they fail to quit or DNA due to potential drug changes that may have been made. *See Appendix D for letter template.*  *Please see Appendix E* for additional information on medication interaction and any action the clinician needs to take when client is stopping smoking.  Please note this is not an exhaustive list.   * Adenosine * Adrenergic agonists and antagonists * Aminophylline * Antihypertensive drugs * Benzodiazepines * Cinacalcet * Chlorpromazine * Clomipramine * Clozapine * Duloxetine * Erlotinib * Flecainide * Fluphenazine * Fluvoxamine * Haloperidol * Imipramine * Insulin * Lithium * Memantine * Methadone * Olanzapine * Pentazocine * Propranolol * Ropinirole * Tacrine * Theophylline * Tricyclic antidepressents * Warfarin * Zolpidem |
| 1.7 | Action if patient is excluded | * Explain reason for exclusion and refer to GP if appropriate. * Document in patients clinical record * Provide further information and support on alternative options to assist the client in stopping smoking |
| 1.8 | Action if patients declines or does not adhere to care under protocol | * Provide further information and support to assist the client in stopping smoking, and benefits of behavioural support. * Document in patients’ clinical record (including reason if given) |

**Staff Characteristics**

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| 2.1 | Class of health  professional for whom  this protocol is applicable | Use of this protocol is only authorised by the Everyone Health Professional Lead for Smoking Cessation, Brigitte McCormack for Stop Smoking Practitioners who:  1. Have a current certificate of authorisation which is not expired.  2. Have attended training on this protocol in the last 12 months.  3. Are Registered Practitioners on the NCSCT Register  Stop Smoking Practitioners will sign to acknowledge they have read this protocol, have received appropriate training and are competent to use it; *see Appendix* |
| 2.2 | Individual responsibilities | Stop Smoking Practitioners have a responsibility for their own development. All staff are required to demonstrate that they possess the knowledge, skills and abilities required for safe and effective practice without direct supervision.  Stop Smoking Practitioners are responsible for maintaining stock control for their allocated clinics. They will be responsible for making sure the correct amount of stock is available to run the clinic efficiently. Whilst in the practitioner’s possession they remain accountable for the NRT.  All Stop Smoking Practitioners are required to use the NRT Direct Supply Order Form to maintain and report stock levels and order NRT supplies.  All Stop Smoking Practitioners have a responsibility to familiarise themselves with and complete all relevant paperwork, training and support will be given. |
| 2.3 | Confidentiality | The public is entitled to expect practitioners to respect and protect the confidentiality of information acquired in the course of their professional duties. The duty of confidentiality extends to any information relating to an individual that a practitioner acquires in the course of their professional duties. Confidential information includes details and medication, both prescribed and not prescribed. |
| 2.4 | Recording supply / patient identifier /audit trail | Records are confidential and should be stored securely and for a length of time in line with local NHS record and record keeping policy.  Records are to be kept using the iMPACT electronic recording database where the client’s informed consent to share information with client’s GP will be recorded.  Clients will be made aware of the records being kept. The database includes the following statement:  NOTE: All client data will be kept securely and in accordance with the Caldicott Guidelines and the Data Protection Act 1998. Information can only be passed to another healthcare professional if this contributes to the provision of effective care. |
| 2.5 | Guidance developed by:  Contact information: | Brigitte McCormack  Everyone Health  2 Watling Drive  Sketchley Meadows  Hinckley  Leicestershire  LE10 3EY  Tel: 01480 278666  Email: BrigitteMcCormack@everyonehealth.co.uk |

**3. Treatment**

**3.1 Name of medicine**

Nicotine Replacement Therapy.

**3.2 Form, Administration and Dosage**

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| Product | | Dose and Directions | Specific written and verbal advice to client | Specific Side Effects |
| Patch | Nicorette Invisi 16 hour patch 25mg/15mg/10mg  Legal Classification = GSL  Recommended Pack Size =7  Formulary for recommended pack size = £10.37  Storage = store below 25c | Directions: one patch to be applied on waking and kept on for 16 hours.  Clients smoking over 10 cigarettes per day are recommended to start on:  25 mg /16 hours patch (Step 1) using one patch daily for 8 weeks  15 mg/16 hours patch (Step 2) should be used daily for 2 weeks  10 mg/16 hours patch (Step 3) daily for 2 weeks.  Lighter smokers (i.e. those who smoke less than 10 cigarettes per day) are recommended to:  Start at Step 2 15 mg/16 hour patch for 8 weeks  Followed by step 3 10 mg/16 hour patch for the final 4 weeks.  All patches should be removed after 16 hours (usually at bedtime).  Maximum period of treatment: 12 weeks per intervention | * Read and adhere to product information leaflet that accompanies NRT product * The patch should be applied once a day, normally in the morning, to a clean, dry, non-hairy area of skin e.g. on the hip, or upper arm. Allow at least seven days before replacing the patch on a previously ‘used’ area. Place the patch in the palm of the hand and apply onto the selected area and hold in place for 10-20 seconds. * Patches should not be applied to broken or inflamed skin. Care should be taken during handling and in particular contact with the eyes and nose avoided. * Once the patch is used it should be folded in half and disposed of carefully. * Clients should never alter the dose of the patch by cutting it up. * Exercise may increase the absorption of nicotine and therefore side effects * Refer to cautions and contraindications category listed in 1.5 | Skin reactions. Discontinue use if severe.  Sleep disturbance including abnormal dreams and insomnia (especially 24 hour patch)  Headaches, dizziness, nausea and vomiting  (See SmPC. for full list of side effects.) |
| NiQuitin - 24 hour patch 21mg/14mg/7mg  Legal Classification = GSL  Recommended Pack Size =7  Formulary for recommended pack size = £9.97  Storage = store below 25c | Directions:  For individuals smoking more than 10 cigarettes per day:  Apply each patch every 24 hours using the following regime  Step 1 NiQuitin 21mg First 6 weeks  Step 2 NiQuitin 14mg Next 2 weeks  Step 3 NiQuitin 7mg Last 2 weeks  Maximum period of treatment: 10 weeks per intervention  Directions for individuals smoking less than 10 cigarettes /day:  Step 2 NiQuitin 14mg First 6 weeks  Step 3 NiQuitin 7mg Last 2 weeks  Maximum period of treatment: 8 weeks per intervention |
| Nicotinell - 24 hour patch 21mg/14mg/7mg  Legal Classification = GSL  Recommended Pack Size =7  Formulary for recommended pack size = £9.12  Storage = store below 25c | Directions for individuals smoking more than 20 cigarettes /day:  Nicotinell 21mg patch applied every 24 hours for 3-4 weeks  Nicotinell 14mg patch applied every 24 hours for 3-4 weeks  Nicotinell 7mg patch applied every 24 hours for 3-4 weeks  Maximum period of treatment: 12 weeks per intervention  Directions for individuals smoking less than 20 cigarettes /day:  Nicotinell 14mg patch applied every 24 hours for 3-4 weeks  Nicotinell 7 mg patch applied every 24 hours for 3-4 weeks  Maximum period of treatment: 8 weeks per intervention |
| Gum | Nicorette Gum 2mg, 4mg & 6mg  Legal Classification = GSL  Recommended Pack Size =105  Formulary for recommended pack size = 11.63  Storage = Store below 25c | Directions:  2mg dose is recommended for those smoking under 20 cigarettes per day  4mg dose is recommended for those smoking over 20 cigarettes per day  6mg dose is recommended for highly dependent smokers who require enhanced craving relief compared to 4mg gum.  Use the gum whenever there is an urge to smoke to maintain complete abstinence from smoking.  Sufficient gums should be used, usually 8-12 per day, up to a maximum of 15.  For those using the 6 mg Gum, switching to the 2 or 4 mg Gums may be helpful when stopping treatment or reducing the number of gums used each day.  When daily use is 1-2 gums, use should be stopped.  The “chew and rest” technique should be used to absorb the nicotine from the gum. After about 30 minutes of such use, the gum will be exhausted.  Maximum period of treatment: 12 weeks per intervention | * Read and adhere to product information leaflet that accompanies NRT product * Gum should be chewed until the taste becomes strong and then ‘parked’ between the gum and cheek until the taste fades. * Recommence chewing once the taste has faded. This ‘chewrest-chew’ technique should be applied for 30 minutes. * Use of acidic beverages such as coffee or soda may decrease the absorption of nicotine. Acidic beverages should be avoided for 15 minutes prior to chewing the gum. * Liquorice flavoured products are not suitable for pregnant women * The product may not be suitable for clients with dentures. * Oral products may exacerbate symptoms of GI disease. * Refer to cautions and contraindications category listed in 1.5 | Throat irritation, increased salivation, hiccups, dizziness, headaches jaw muscle ache  See SmPC. for full list of side effects |
| Nicotinell Gum 2mg and 4mg  Legal Classification = GSL  Recommended Pack Size = 96  Formulary for recommended pack size = £10.26  Storage = store below 25c | Directions:  2mg dose is recommended for those smoking under 20 cigarettes per day  4mg dose is recommended for those smoking over 20 cigarettes per day  Sufficient gums should be used, usually 8-12 per day, up to a maximum of 15  The Chew and rest technique should be used for a duration of 30 minutes per piece.  Maximum period of treatment: 12 weeks per intervention |  |
| NiQuitin Gum 2mg and 4mg  Legal Classification = GSL  Recommended Pack Size = 96  Formulary for recommended pack size = £8.55  Storage = store below 25c | Directions:  NiQuitin 4 mg Mint Gum is suitable for smokers who have their first cigarette of the day within 30 minutes of waking. The  NiQuitin 2mg dosage is appropriate for those who have their first cigarette more than 30 minutes after waking.  Sufficient gums should be used each day, usually 8 12, up to a maximum of 15 for either.  The gums should be used whenever there is an urge to smoke according to the “chew and rest” technique described on the pack.  After about 30 minutes of such use, the gum will be exhausted. Not more than 15 pieces of the chewing gum may be used each day.  When daily use is 1 2 gums, use should be stopped  Maximum period of treatment: 12 weeks per intervention |
| Lozenge | Nicotinell Lozenge 1mg and 2mg  Legal Classification = GSL  Recommended Pack Size =  Formulary for recommended pack size = £10.37  Storage = do not store above 25c | Directions:  Nicotinell Mint 2 mg lozenge is intended to be used by smokers with a strong or very strong nicotine dependency i.e. at least over 20 cigarettes per day and those who have previously failed to stop smoking with the aid of NRT. Low to medium dependency smokers are recommended to try 1mg dose (less than 20 cigarettes per day).  Lozenges should be sucked until the taste is strong and then ‘parked’ between the gum and the cheek until the taste fades. Once faded then sucking should recommence.  On average 8-12 lozenges daily, not exceeding 15 lozenges per day for 2mg dose and 30 lozenges per day for 1mg dose.  One lozenge every 1-2 hours in week 1-6  Then one lozenge every 2-4 hours weeks 7-9  Reducing down to 1-2 a day by week 12.  Maximum period of treatment: 12 weeks per intervention | * Read and adhere to product information leaflet that accompanies NRT product * Simultaneous use of coffee, acid drinks and soft drinks may decrease absorption of nicotine and should be avoided for 15 minutes prior to sucking lozenge. * Oral products may exacerbate symptoms of GI disease. * Lozenges are not suitable for under 18’s, those required to follow a * Low sodium diet and those with phenylketonuria (PKU). * Liquorice lozenge products are not suitable for pregnant women * Refer to cautions and contraindications category listed in 1.5 | Throat irritation, increased salivation, hiccups, coughing, sore mouth or throat.  See SmPC. for full list of side effects. |
| NiQuitin Lozenge 2mg and 4mg  Legal Classification = GSL  Recommended Pack Size = 72  Formulary for recommended pack size = £9.97  Storage = do not store above 25c | Directions: For individuals who do not have the urge to smoke within 30minutes of waking; consider initiating on 2mg lozenge. For those who need to smoke within 30 minutes of waking; consider 4mg lozenge.  Step 1: Weeks 1 to 6 – Initial treatment period: 1 lozenge every 1 to 2 hours  Step 2: Weeks 7 to 9 – Step down treatment period: 1 lozenge every 2 to 4  hours  Step 3: Weeks 10 to 12 - Step down treatment period: 1 lozenge every 4 to 8  Hours  During weeks 1-6 it is recommended that a minimum of 9 lozenges and a maximum of 15 lozenges per day are taken.  One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved (approximately 20 – 30 minutes). The lozenge should not be chewed or swallowed whole. |
| Nicorette Cools Lozenge 2mg and 4 mg  Legal Classification = GSL  Recommended Pack Size = 80  Formulary for recommended pack size = £11.48  Storage = do not store above 25c | Directions:  Nicorette Cools 2 mg Lozenge is suitable for smokers who smoke 20 or less cigarettes per day. The 4 mg Cools Lozenge is suitable for smokers who smoke more than 20 cigarettes per day. Nicorette Lozenge should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur.  Most smokers require 8 to 12 lozenges per day, not to exceed 15 lozenges.  One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved. You should not chew or swallow the lozenge. You should not eat or drink while a lozenge is in the mouth  A tapering down dose following the recommended schedule is advised:  One lozenge every 1-2 hours in week 1-6  Then one lozenge every 2-4 hours weeks 7-9  Reducing down to 1-2 a day by week 12.  Maximum period of treatment: 12 weeks per intervention |
| Mini Lozenge | NiQuitin Minis Lozenges 1.5mg & 4mg  Legal Classification = GSL  Recommended Pack Size = 60  Formulary for recommended pack size = £9.57  Storage = Do not store above 30c | Directions: 1.5mg (suitable for those smoking 20 or less cigarettes per day), 4mg (suitable for those smoking more than 20 per day).  Use the lozenges whenever there is an urge to smoke.  Sufficient lozenges should be used each day, usually 8 12, up to a maximum of 15.  Continue use for up to six weeks to break the habit of smoking, and then gradually reduce lozenge use. When daily use is 1-2 lozenges, use should be stopped.  Maximum period of treatment: 12 weeks per intervention | * Read and adhere to product information leaflet that accompanies NRT product * One lozenge should be placed in the mouth and allowed to dissolve. Periodically, the lozenge should be moved from one side of the mouth to the other, and repeated, until the lozenge is completely dissolved (approximately 10 minutes). * The lozenge should not be chewed or swallowed whole. Users should not eat or drink while a lozenge is in the mouth. * Oral products may exacerbate symptoms of GI disease. * Minis maybe given to under 18’s * Refer to cautions and contraindications category listed in 1.5 | Nausea, hiccups, flatulence, GI disturbance, vomiting, diarrhoea, dyspepsia, fatigue, malaise, sleep disorders  (See SmPC. for full list of side effects.) |
| Micro tablet | Nicorette Microtab 2mg sublingual tablets  Legal Classification = GSL  Recommended Pack Size = 100  Formulary for recommended pack size = £13.12  Storage = Do not store above 25c | Directions:  The initial dose is based on the individual's nicotine dependence. The tablet is used sublingually with a recommended dose of one tablet per hour, or for heavy smokers (smoking more than 20 cigarettes per day), two tablets per hour.  Most smokers require 8 to 12 or 16 to 24 tablets per day, not to exceed  40 tablets per day.  The nicotine dose should then be gradually reduced, by decreasing the total number of tablets used per day. The treatment should be stopped when the daily consumption is down to one or two tablets.  Maximum period of treatment: 12 weeks per intervention | * Read and adhere to product information leaflet that accompanies NRT product * Tablets should be placed under the tongue and allowed to dissolve slowly. * Oral products may exacerbate symptoms of GI disease. * Refer to cautions and contraindications category listed in 1.5 | Throat irritation, unpleasant taste, dizziness, palpitations, coughing, hiccups.  (See SmPC. for full list of side effects.) |
| Inhalator | Nicorette Inhalator 15mg cartridge plus mouthpiece  Legal Classification = GSL  Recommended Pack Size = 36  Formulary for recommended pack size = £24.03  Storage = Store below 25c | Directions:  Nicorette Inhalator should be used whenever the urge to smoke is felt or to prevent cravings in situations where these are likely to occur.  Smokers should replace all their cigarettes with the Inhalator.  Use 3-6 cartridges daily for up to 8 weeks. Then reduce the dose to 1-3 cartridges over the next 2 weeks, and then reduce the dose to 0 over the final 2 weeks.  Maximum number of inhalator cartridges per day is 6.  Each cartridge can be used for approximately eight 5-minute sessions, with each cartridge lasting approximately 40 minutes of intense use. The more the subject is able to use the inhalator, the easier it will be to quit smoking completely.  When a patient draws air into the mouth through the mouthpiece, nicotine is vaporised and absorbed via the lining of the mouth. Minimal nicotine reaches the lungs. The amount of nicotine from a puff is less than that from a cigarette. To compensate for less nicotine delivery from a puff it is necessary to inhale more often than when smoking a cigarette. The number of cartridges, frequency, puffing/inhalation time and technique does vary between individuals.  The actual time that the cartridge is active depends on the intensity of use. After about 40 minutes of intense use the maximal dose is achieved and it is about then that the nicotine amounts released from the cartridge begin to fall away, such that the cartridge is rejected by the user.  Maximum period of treatment: 12 weeks per intervention | * Read and adhere to product information leaflet that accompanies NRT product. * Air should be drawn into the mouth through the mouthpiece. Clients should be warned that the inhalator requires more effort to inhale than a cigarette and that less nicotine is delivered per inhalation. * The inhalator is best used at room temperature as nicotine delivery is affected by temperature. * Used cartridges will contain residual nicotine and should be disposed of safely. Advise the client to keep them in the case and dispose of them in household rubbish and keep away from children/pets etc. * Potential choking hazard: This product contains some small parts. * Patients with obstructive lung disease may find use of the Inhalator difficult. Other oral forms of NRT may be preferred in such cases. * Nicorette Inhalator should be used with caution in patients with chronic throat disease and lung disease. * Inhaled products may exacerbate symptoms of Gastro-intestinal disease. * Once inserted into the mouthpiece the cartridge should be disposed of within 48 hours even if it has not been used. * Refer to cautions and contraindications category listed in 1.5 | Cough, headache, throat and mouth irritation, dizziness, nasal congestion, stomach discomfort, hiccups, nausea and vomiting    (See SmPC. for full list of side effects.) |
| Nasal Spray | Nicorette Nasal Spray (10ml)  Legal Classification = GSL  Recommended Pack Size = 1  Formulary for recommended pack size = £13.80  Storage = do not store above 25c  Storage = No special temperature conditions. Should be stored protected from light | **Nicorette Nasal Spray (10ml)**  Each spray delivers 0.5mg of nicotine - 200 sprays per bottle  Directions:  1) Remove the protective cap.  2) Prime Nicorette Nasal Spray by placing the nozzle between first and second finger with the thumb on the bottom of the bottle. Press several times firmly and quickly until a fine spray appears (up to 7-8 strokes).  Important: Point the spray safely away when priming it. Do not prime it near children or pets.  3) Insert the spray tip into one nostril, pointing the top towards the back of the nose. Press firmly and quickly. Give a spray into the other nostril.  4) Put on the protective cap  On commencing treatment the patient uses the spray to treat craving as required, subject to a limit of one spray to each nostril twice an hour.  Each spray delivers 0.5 mg of nicotine, about half of which is absorbed.  The daily limit of use is 32mg of nicotine (64 sprays) which is the equivalent of two sprays to each nostril every hour for 16 hours.  For 8 weeks the patient uses the spray as required, subject to the maximum described above, to relieve craving.  After this period the patient reduces usage until after 4 more week’s treatment has ended. It is suggested that after 2 weeks into this period usage will have been reduced by a half and usage be zero by the last day.  The patient should understand the aim of decreasing the use of the spray to make a final break with nicotine at the end of the course, and also accept that for the first few days of the course nasal irritation may be unpleasant.  Maximum period of treatment: 12 weeks per intervention | * Read and adhere to product information leaflet that accompanies NRT product * Warn of possible local effects but also that these tend to lessen within a few days. * Warn patient that the bottle may need priming before use * Advice on correct use of spray * The nasal spray should not be used whilst the user is driving or operating machinery as sneezing and watering eyes could contribute to accidents. * Spray products may exacerbate symptoms of Gastro-intestinal disease. * This product must only be used in combination with other NRT products under the advice of a healthcare professional i.e. nurse, midwife, doctor * Not recommended for those with nasal problems e.g. polyps, nose bleeds * Bronchial asthma: A few cases of exacerbation of brochospasm in patients with bronchial asthma have been reported. Use of the spray in patients with hyperreactive airways is not recommended * Refer to cautions and contraindications category listed in 1.5 | Nose and throat irritation, nosebleeds, watering eyes, ear sensations, dizziness, coughing, sneezing  (See SmPC. for full list of side effects.) |
| Mouth Spray | Nicorette QuickMist Mouth spray – 1 mg spray  Legal Classification = GSL  Recommended Pack Size = 1  Formulary for recommended pack size = £12.12  Storage = do not store above 25c | 150 sprays per bottle  This spray is a colorless to light yellow solution with a scent of peppermint. If you are using mouth spray for the first time or if you have not used the spray for 2 days, you must first prime the spray pump.  Priming:  1. Point the spray safely away from you and any other adults, children or pets that are near you.  2. Press the top of the spray with your index finger 3 times until a fine spray appears.  Note: priming reduces the number of sprays you may get from the spray.  Directions: After priming, point the spray nozzle as close to the open mouth as possible. Press the top of the dispenser and release one spray into your mouth, avoiding the lips. Do not inhale while spraying to avoid getting spray down your throat. For best results, do not swallow for a few seconds after spraying.  Use 1 or 2 sprays when cigarettes normally would have been smoked or if cravings emerge. If after the first spray cravings are not controlled within a few minutes, a second spray should be used. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays.  Most smokers will require 1-2 sprays every 30 minutes to 1 hour. You may use up to 4 sprays per hour. Do not exceed 2 sprays per dosing episode and 64 sprays (4 sprays per hour over 16 hours) in any 24-hour period.  Use the following weaning down process:  • Weeks 1-6: 1-2 sprays when you would normally smoke a cigarette or have cravings to smoke (use the second spray if your cravings are not reduced within a few minutes) For many smokers this means 1-2 sprays every 30minutes to 1 hour.  • Week 7-9: Start reducing the number of sprays per day By the end of week 9 you should be using HALF the average number of sprays per day that you used in weeks 1-6  • Week 10 -12: Continue reducing the number of sprays per day so that you are not using more than 4 sprays per day during week 12  Maximum period of treatment: 12 weeks per intervention | * Read and adhere to product information leaflet that accompanies NRT product * The patient should not eat or drink when administering the spray * The mouth spray contains small amounts of ethanol (alcohol), less than 100 mg per spray * Care should be taken not to spray the eyes whilst administering the mouth spray * Warn patient that the bottle may need priming before use * Advice on correct use of spray * Oral products may exacerbate symptoms of Gastro-intestinal disease. * Refer to cautions and contraindications category listed in 1.5 | Dysgeusia (distortion of taste), headache, Pre syncopal symptoms (light headiness), dizziness, paraesthesia (tingling sensation) hiccups, nausea and vomiting symptoms, dyspepsia, constipation. Oral soft tissue pain and paraesthesia, stomatitis, salivary, cough, naso -pharyngistis, hypersecretion, burning lips, dry mouth, gingival bleeding. Increased frequency of apthous ulcer (which also can be an effect of stopping smoking).  (See SmPC. for full list of side effects.) |

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| 3.4 | Electronic Cigarettes | At the time of writing, no E-cigarette is licensed as a smoking cessation aid.  The use of E-cigarettes with NRT is now possible but Stop Smoking Practitioners cannot recommend or supply them. |
| 3.3 | Supply and Length of Treatment | NRT will be issued directly by the Stop Smoking Practitioner to the client that is receiving support not to any 3rd party.   * Stop Smoking Practitioners will supply NRT directly to the client. Supplies will be issued by Everyone Health. * For a maximum of 12 weeks in total. * For a maximum of 2 weeks at a time. Please see *Appendix E* for Approved NRT products, pack sizes and maximum amount supplied for 2 week duration * If a client is not abstinent after 2 weeks further NRT, however supplied, should not be supplied until the client can demonstrate a commitment to quitting.   Stop Smoking Practitioners should order replacement NRT stock via the Clinical Contact Centre Lead.  If the practitioner does not have a product a client wishes to use the client will be informed that the practitioner will order the product and it will be posted to the client via our Clinical Contact Centre. All NRT products that are posted will be in tamper proof plastic envelopes, delivery will be tracked and signed for and the name of the person who signs for the products will be cross referenced with the client.  In the cases of people not able to make weekly or fortnightly appointments it will be the practitioner’s discretion of how best to continue NRT distribution. |
| 3.4 | Side Effects / Adverse Reactions | Side effects from nicotine replacement therapy are usually transient but may include some of the list below, most of which are a consequence of stopping smoking;  • Nausea  • Dizziness  • Headaches  • Cold and flu-like symptoms  • Palpitations  • Dyspepsia and other gastro-intestinal disturbances  • Hiccups  • Insomnia  • Vivid dreams  • Myalgia  • Chest pain  • Blood pressure changes  • Anxiety and irritability  • Somnolence and impaired concentration  • Dysmenorrhoea  Product-specific side effects are detailed in the SPCs. |
| 3.5 | Advice to Clients | Advice to clients on issuing NRT supply should include specific product advice plus the following general advice on:  • Withdrawal symptoms and the role of NRT  • Possible changes in the body on stopping smoking, e.g. weight gain  • Possible side effects of NRT  • The effects of smoking tobacco whilst using NRT  • Written information on NRT products supplied, self-help leaflets and where to obtain more information |
| 3.6 | Exemption from prescription charges | The Stop Smoking Practitioner supplying the NRT must ask clients who are exempt from prescription charges for evidence. Reason for exemption will be captured on the data management system.  Where a patient is not exempt from prescription charges the Stop Smoking Practitioner must collect such charges as would apply in the case of the supplied items being on a prescription i.e. one charge per different formulation supplied etc. |
| 3.7 | Procedure for reporting Adverse Drug Reactions (ADRs) | Any serious reaction should be reported to the MHRA through the yellow card scheme in the normal manner. It is the responsibility of the Stop Smoking Practitioner to identify a suspected ADR and to report it by telephone on 0808 100 3352 or online at www.yellowcard.gov.uk  The Stop Smoking Practitioner should:   * Inform client to stop using NRT * Inform client’s GP * Report incident using the Adverse Event Report system |

**4. Further Information / Special Considerations**

|  |  |  |
| --- | --- | --- |
| 4.1 | Adults | For clients aged 16 and over NRT can be used as described on the product depending on their Nicotine dependence and product specification.  Certain factors, including gender, pregnancy and oral contraceptives, can affect the rate at which a smoker metabolises nicotine. This may have implications for the choice and strength of pharmacotherapy required. |
| 4.2 | Children | NRT is not licensed for use in those under 12 years of age. For people aged 13-16 year olds please assess and complete a Fraser Competency Assessment so that young people under the age of 16 can consent to medical treatment if they have sufficient maturity and judgement to enable them fully to understand what is proposed. Please see *Appendix G* for Fraser Competency Assessment  Mono therapy NRT should not be given for a period longer than 12 weeks to 12-18 year olds. |
| 4.3 | Pregnancy | Tobacco users who are pregnant and are unable to stop smoking without the use of NRT is supported by NICE guidance.  The process for dealing with pregnant women is as follows:   * Behavioural support as a first line of treatment for those who have never tried to stop smoking, and ideally they should try to give up smoking without using NRT. * NRT can be used if above is unsuccessful. Oral products are the first line of treatment for these women (but not liquorice flavoured products). Intermittent oral products are recommended as they give the foetus a break from nicotine. However it is well documented that many pregnant women will experience nausea and will not be able to tolerate oral NRT products. * If oral products are unsuccessful or cannot be tolerated due to nausea, 16 hour patches can be used, but not a 24 hour patch. * Fast metabolism of nicotine from NRT products means that some quitters will need higher doses to control their cravings and other withdrawal symptoms. This is especially relevant to pregnant smokers who may need higher doses of NRT but may be concerned or cautious about using it. Where appropriate, stop smoking practitioners should advise pregnant women to use NRT in line with the product specification but should be especially careful about this client group under-dosing or stopping the treatment early.   Many pregnant women who access the service will have taken some of the steps above before their appointment; this should be taken into account at the initial assessment.  Always ensure the risks/benefits of stopping smoking have been discussed in full and consent form for treatment has been completed. |
| 4.4 | Breastfeeding | NRT can be used by women who are breast-feeding. If possible, patches should be avoided. NRT products taken intermittently are preferred as their use can be adjusted to allow the maximum time between their administration and feeding of the baby, to minimise the amount of nicotine in the milk. 24 hour patches and liquorice flavoured gum are not recommended. Patches should be removed and replaced every day. |
| 4.5 | Diabetes Mellitus | Diabetic patients should be advised to monitor their blood sugar levels more closely than usual when starting NRT. |
| 4.6 | Renal or hepatic impairment | NRT should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as there is a potential for increased adverse effects. |
| 4.7 | Mental Health | Stopping smoking changes the plasma levels of anti-psychotic medication, which could lead to a worsening of existing mental illness. This is a medical caution. Please see 1.6 for a full list of potential drug interactions. |
| 4.8 | Other Considerations | Allergy to the products used to formulate the NRT product. NRT Gums are not suitable for denture wearers or for patients with stomach problems. Patches are unsuitable for patients with dermatological disorders. Patches should be removed and replaced every day. Lozenges are sugar-free and therefore suitable for diabetic patients if patches are not suitable. Care should be taken with inhalation cartridges in clients with obstructive lung disease, chronic throat disease, or bronchospastic disease. Nasal sprays can worsen bronchial asthma. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Full Name** | **Designation** | **Date competency gained** | **Date of signing** | **Signature** |
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**Appendix A - Template for Staff Register**

Protocol Name: Protocol for the direct supply of Nicotine Replacement Therapy (NRT) by Everyone Health Stop Smoking Practitioners in the London Borough of Waltham Forest.

The staff listed below have signed to acknowledge that they have read this clinical protocol in full, have received appropriate training and updates and are competent to use it.

**Appendix B – Medical Questionnaire for the Direct Supply of NRT under Protocol**

|  |  |  |  |
| --- | --- | --- | --- |
| **CONTRAINIDCATIONS: The following clients cannot have NRT under the protocol** | | |  |
| **Is the client:** |  |  |  |
| Suitable for the Level 3 intervetion | Yes |  |  |
| Under 12 years of age? | Yes | No | If YES to any of these questions, NRT should not be issued |
| Taking Buproprion (Zyban) or Varenicline (Champix) | Yes | No |
| Any known serious reaction to nicotine? | Yes | No |
| Suffered an acute cardio-vascular event in the last 4 weeks and have not had their NRT treatment initiated whilst they were in hospital or do not have a written recommendation from their consultant for NRT treatment. | Yes | No |
| Contraindications for Patches only   * Serious reaction to NRT patches previously?(If client has had a reaction or skin condition such as Eczema, Chronic Dermatitis, Psoriasis & Urticeria other products may be more suitable) | Yes | No | If YES to any of these questions a different NRT which isn’t contraindicated should be chosen |
| Contraindications for Mouth Spray Only  Is the client undergoing treatment for alcohol dependency? | Yes | No |
| Contraindications for Nasal spray only  Does the client suffer with a chronic nasal disorders such as polyposis, vasomotor rhinitis and perennial rhinitis. |  |  |
| Assessment for suitability for NRT under the protocol   * Is the client under 16 years of age? * If yes have you completed the Fraser Competency Assessment | Yes | No |  |
| Yes | No | Not Applicable |
| CAUTIONS UNDER PROTOCOL | | | |
| Pregnant/breast feeding   * NRT can be used if client has tried unsuccessfully without * Preferably use behavioural support first followed by oral products (not liquorice flavour) * If experiencing nausea -16 hour Patch can be used if unable to tolerate oral products. | Yes | No | Not Applicable |
| Does the client have a history of liver problems? | Yes | No |  |
| Does the client have a history of kidney problems? | Yes | No |  |
| Does the client have a history of thyroid problems? | Yes | No |  |
| Does the client have a history of epilepsy? | Yes | No |  |
| Does the client have a history of seizures? | Yes | No |  |
| Does the client have a history of phaeochromocytoma? (Tumor affecting the adrenal medulla) | Yes | No |  |
| Does the client have a history of active peptic ulcer disease  (stomach ulcers)? (Oral products may worsen this condition; ensure the client is aware, patch may be more appropriate) | Yes | No |  |
| Is the client taking any of the following medications?  Adenosine, Adrenergic agonists and antagonists, Aminophylline, Antihypertensive drugs, Benzodiazepines, Cinacalcet, Chlorpromazine, Clomipramine, Clozapine, Duloxetine, Erlotinib, Flecainide, Fluphenazine, Fluvoxamine, Haloperidol, Imipramine, Insulin, Lithium, Memantine, Methadone, Olanzapine, Pentazocine, Propranolol, Ropinirole, Tacrine, Theophylline, Tricyclic antidepressents, Warfarin, Zolpidem | Yes | No |  |
| **If Yes to any of the above, please send cautions letter to GP.**  **If clients DNA, please send letter informing GP as medications may have been changed.** | | | |

**Appendix C – Letter to GP for clients on programme and in caution category**

Waltham Forest Stop Smoking Service

2 Watling Drive

Sketchley Meadows

Hinckley

Leicestershire

Phone: 0333 005 0095

Fax: 0208 181 6301

Dear XXXXXX

Patient Name: XXXXXXXXXXX DOB: XX/XX/XXXX Postcode: XXXX XXX

**Waltham Forest Stop Smoking service is provided by non-clinicians**

The above named client is accessing the Waltham Forest Stop Smoking Service and has started the standard treatment programme and would like to use Nicotine Replacement Therapy (NRT) as part of the 12 week programme.

NRT is usually used for 8-12 weeks. If the client remains abstinent when returning to the service to receive behavioural support, a further 2 weeks of NRT will be supplied, and this is ongoing until the programme has been completed.

**The client has disclosed that they have the following condition(s):**

Choose an item.

Choose an item.

Choose an item.

Choose an item.

**and/or are taking the following medication(s)**

Choose an item.

Choose an item.

Choose an item.

Choose an item.

Choose an item.

Choose an item.

**Action by the GP: For the medications highlighted above it may be necessary to make a dose adjustment as smoking can affect the metabolism of these medications. The conditions are listed by the service as a caution and our protocol therefore requires us to inform the GP that NRT has been commenced**

Please note that if the client starts smoking again their medication may need to be reviewed again, thus we will inform you if this client defaults from the service or fails in their quit attempt.

Please contact us if you have any queries.

*Name of Stop Smoking Practitioner,*

*Contact Telephone Number,*

*Signature*

**Appendix D – Letter to GP to review medication subsequent to DNA / Failed Quit Attempt**

Waltham Forest Stop Smoking Service

2 Watling Drive

Sketchley Meadows

Hinckley

Leicestershire

Phone: 0333 005 0095

Fax: 0208 181 6301

Dear XXXXXX

Patient Name: XXXXXXXXXXX DOB: XX/XX/XXXX Postcode: XXXX XXX

Dear Dr

I am writing regarding the above clients stop smoking attempt with the Everyone Health Waltham Forest Stop Smoking Service

Unfortunately due to this patients non-attendance / continuing to smoke. I need to advise you that a previous letter may have caused you to adjust some of the clients medications due to stopping smoking, and this may now need reviewing.

If you have any queries please contact me on the number shown below.

*Name of Stop Smoking Practitioner*

*Contact telephone number:*

*Signature:*

**Appendix E – Dose adjustment of medications when stopping smoking**

Cigarette smoking can interact with some medicines. This is mainly due to polycyclic aromatic hydrocarbons in cigarette smoke that stimulate cytochrome P450 enzymes, particularly CYP1A2. A number of medicines that are metabolised via CYP1A2, may consequently be more rapidly metabolised in smokers.

The majority of interactions are not clinically significant but the potential for interaction should be borne in mind if a patient starts or stops smoking

|  |  |  |  |
| --- | --- | --- | --- |
| **Drug Name** | **Nature of Interaction** | **Clinical Relevance** | **Action to take when stopping smoking** |
| Adenosine | Nicotine from nicotine-replacement therapy can enhance the effect of adenosine. Smoking may have a similar effect. | Low | None |
| Adrenergic agonists and antagonists | Historically, an interaction between smoking and adrenergic receptor antagonists was included in the prescribing information for nicotine replacement products. | Nil | None |
| Aminophylline | Smokers require higher doses of aminophylline than non-smokers as smoking can increase aminophylline clearance. | High | Aminophylline is monitored therapeutically in terms of plasma-theophylline concentrations. Dose adjustments are likely to be necessary if smoking started or stopped during treatment. |
| Antihypertensive drugs | Smokers may require higher doses of antihypertensive drugs. |  | Dose adjustments may be necessary if smoking started or stopped during treatment |
| Benzodiazepines | Smokers taking benzodiazepines may experience less drowsiness than non-smokers. Results from pharmacokinetic studies have been mixed and the interaction, if any exists, may be due to stimulation of the central nervous system from smoking. | Low | Patients may experience an enhanced effect of benzodiazepines after stopping smoking. If so, consider reducing the dose. |
| Cinacalcet | Cinacalcet is metabolised partly via CYP1A2. Dose adjustment may be required if a patient starts or stops smoking. There are no documented cases of an interaction. | Low | Monitor parathyroid hormone levels and adjust the dose accordingly. |
| Chlorpromazine | Chlorpromazine is metabolised principally via CYP1A2. Smokers have lower serum levels of chlorpromazine compared with non-smokers. | Moderate | Be alert for increased adverse effects of chlorpromazine (e.g. dizziness, sedation, extra-pyramidal symptoms). If adverse effects occur, reduce the dose as necessary. |
| Clomipramine | Serum levels of clomipramine are lower in smokers than in non-smokers but the concentration of free drug rises which appears to offset the effects of this interaction | Low | Be alert for increased adverse effects of the antidepressant. If adverse effects occur, reduce the dose as necessary. |
| Clozapine | Clozapine is metabolised principally via CYP1A2 and clearance is increased in smokers. Serum clozapine levels are reduced in smokers compared with non-smokers; smokers may need higher doses.  There have been case reports of adverse effects in patients taking clozapine when they have stopped smoking. | High | Monitor serum drug levels before stopping smoking and one or two weeks after stopping smoking.  Be alert for increased adverse effects of clozapine. If adverse effects occur, reduce the dose as necessary. |
| Duloxetine | Duloxetine is metabolised via CYP2D6 and CYP1A2. Serum levels of duloxetine are lower in smokers, but the difference is not considered to be clinically relevant. | Low | None |
| Erlotinib | Plasma levels of erlotinib are decreased in current smokers compared with non-smokers. Smokers should be encouraged to stop before erlotinib therapy is initiated. | Moderate | None |
| Flecainide | Smoking increases the clearance of flecainide. Smokers appear to need higher doses of flecainide, compared with non-smokers. | Low | Be alert for dose-related adverse effects of flecainide such as dizziness and visual disturbances. If adverse effects occur, reduce the dose as necessary. |
| Fluphenazine | Studies suggest that smokers have increased fluphenazine clearance compared with non-smokers and may require higher doses, but have not shown any difference in behavioural and adverse effects. | Low | Be alert for increased adverse effects of fluphenazine (e.g. drowsiness, extra-pyramidal symptoms). If adverse effects occur, reduce the dose as necessary. |
| Fluvoxamine | Fluvoxamine is the only Selective Serotonin RI expected to interact with smoking.  Fluvoxamine is metabolised by CYP1A2 and plasma levels may be lower in smokers than non-smokers. Smokers might need higher doses than non-smokers. | Low | Be alert for increased adverse effects of fluvoxamine. If adverse effects occur, reduce the dose as necessary. |
| Haloperidol | Studies suggest that smokers have increased haloperidol clearance compared with non-smokers and may require higher doses, but have not shown any difference in behavioural and adverse effects. | Low | Be alert for increased adverse effects of haloperidol (e.g. drowsiness, extra-pyramidal symptoms). If adverse effects occur, reduce the dose as necessary. |
| Imipramine | Serum levels of imipramine are lower in smokers than in non-smokers but the concentration of free drug rises which appears to offset the effects of this interaction | Low | Be alert for increased adverse effects of the antidepressant. If adverse effects occur, reduce the dose as necessary. |
| Insulin | Smoking is associated with poor glycaemic control in patients with diabetes. Smokers may require higher doses of insulin but the mechanism of any interaction is unclear. | Moderate | If a patient with insulin-dependent diabetes stops smoking, their dose of insulin may need to be reduced. Advise the patient to be alert for signs of hypoglycaemia and to test their blood glucose more frequently. |
| Lithium | There is a theoretical indirect interaction between smoking and lithium. Stopping smoking could lead to increased xanthine levels by reducing metabolism of dietary caffeine. Raised xanthine levels could in turn lead to increased lithium excretion. There are no documented cases of an interaction. | Low | None |
| Memantine | There is a theoretical interaction between memantine and smoking but it is not expected to be clinically relevant. | Low | None |
| Methadone | Methadone is metabolised via isoenzymes including CYP1A2.  There has been a case report of respiratory insufficiency and altered mental status when a patient taking methadone for analgesia stopped smoking. | Moderate | Be alert for signs of opioid toxicity and reduce the methadone dose accordingly. |
| Olanzapine | Olanzapine is metabolised principally via CYP1A2 and clearance is increased in smokers. Serum olanzapine levels are reduced in smokers compared with non-smokers; smokers may need higher doses.  There have been case reports of adverse effects in patients taking olanzapine when they have stopped smoking. | High | Be alert for increased adverse effects of olanzapine (e.g. dizziness, sedation, hypotension). If adverse effects occur, reduce the dose as necessary. |
| Pentazocine | Pentazocine metabolism is increased by smoking. Smokers may need higher doses than non-smokers. | Low | None |
| Propranolol | Propranolol metabolism is increased by smoking. Smokers may need higher doses than non-smokers | Low | Stopping smoking may lead to an increase in levels of propranolol. If adverse effects occur the dose may need to be reduced slowly over one week |
| Ropinirole | Ropinirole is metabolised principally via CYP1A2 and smokers may require higher doses than non-smokers. The dose of ropinirole is titrated according to response. | Low | Be alert for increased adverse effects of ropinirole (e.g. nausea, dizziness). If adverse effects occur, reduce the dose as necessary. |
| Tacrine | Tacrine is metabolised principally via CYP1A2 and smokers may require higher doses than non-smokers. | Low | Be alert for increased adverse effects of tacrine (e.g. gastrointestinal effects, hepatotoxicity). If adverse effects occur, reduce the dose as necessary. |
| Theophylline | Theophylline is metabolised principally via CYP1A2. Smokers need higher doses of theophylline than non-smokers due to theophylline’s shortened half-life and increased elimination. Some reports suggest smokers may need twice the dose of non-smokers. | High | Monitor plasma theophylline concentrations and adjust the dose of theophylline accordingly. The dose of theophylline may need to be reduced by about one quarter to one third one week after withdrawal. However, it may take several weeks for enzyme induction to dissipate. Monitor theophylline concentration periodically.  Advise the patient to seek help if they develop signs of theophylline toxicity such as palpitations or nausea. |
| Tricyclic antidepressents | Serum levels of amitriptyline, clomipramine, imipramine and nortriptyline are lower in smokers than in non-smokers, but the concentration of free drug rises, which appears to offset the effects of this interaction. | Low | Be alert for increased adverse effects of the antidepressant. If adverse effects occur, reduce the dose as necessary. |
| Warfarin | Warfarin is partly metabolised via CYP1A2. An interaction with smoking is not clinically relevant in most patients. The dose of warfarin is adjusted according to a patient’s INR (International Normalised Ratio). | Moderate | If a patient taking warfarin stops smoking, their INR might increase so monitor the INR more closely. Advise patients to tell the physician managing their anticoagulant control that they are stopping smoking. |
| Zolpidem | Smoking may lower plasma levels of Zolpidem and heavy smokers may need higher doses | Low | Is patient taking zolpidem stops smoking there may be an increase in the plasma levels which could increase the sedative effect. If this happens, reduce the dose as necessary. |

**Appendix F - Approved NRT products, pack sizes and maximum amount supplied for 2 week duration**

|  |  |  |  |
| --- | --- | --- | --- |
| Product | Strength | Approved Pack Sizes | Maximum Supply for 2 Week Duration |
| Nicorette Chewing Gum (all flavours) | 2mg | 30, 105 | 2 x 105 |
| Nicorette Chewing Gum (all flavours) | 4mg | 30, 105 | 2 x 105 |
| Nicorette Chewing Gum (all flavours) | 6mg | 30, 105 | 2 x 105 |
| Nicorette Cools Lozenge | 2mg | 20, 80 | 2 x 80 |
| Nicorette Cools Lozenge | 4mg | 20, 80 | 2 x 80 |
| Nicorette Inhalator | 15mg | 20, 36 | 3 x 36 |
| Nicorette Invisipatch | 10mg | 7 | 2 x 7 |
| Nicorette Invisipatch | 15mg | 7 | 2 x 7 |
| Nicorette Invisipatch | 25mg | 7 | 2 x 7 |
| Nicorette Quickmist | 1mg | 13.2ml, Duo (2x13.2ml) | 3 x Duo |
| Nicorette Microtab | 2mg | 30, 100 | 6 x 100 |
| Nicorette Nasal Spray | 0.5mg | 10ml | 5 x 10 |
| Nicotinell Chewing Gum | 2mg | 24, 72, 96, 204 | 2 x 96 |
| Nicotinell Chewing Gum | 4mg | 24, 72, 96, 204 | 2 x 96 |
| Nicotinell Lozenge | 1mg | 36, 96 | 5 x 96 |
| Nicotinell Lozenge | 2mg | 36, 96 | 3 x 96 |
| Nicotinell Patch TTS 10 | 7mg | 7 | 2 x 7 |
| Nicotinell Patch TTS 20 | 14mg | 7 | 2 x 7 |
| Nicotinell Patch TTS 30 | 21mg | 7 | 2 x 7 |
| NiQuitin Gum | 2mg | 24, 96 | 2 x 96 |
| NiQuitin Gum | 4mg | 24, 96 | 2 x 96 |
| NiQuitin Lozenge | 2mg | 36, 72 | 3 x 72 |
| NiQuitin Lozenge | 4mg | 36, 72 | 3 x 72 |
| NiQuitin Minis | 1.5mg | 20, 60 | 4 x 60 |
| NiQuitin Minis | 4mg | 20, 60 | 4 x 60 |
| NiQuitin Patch (original and clear) | 7mg | 7 | 2 x 7 |
| NiQuitin Patch (original and clear) | 14mg | 7 | 2 x 7 |
| NiQuitin Patch (original and clear) | 21mg | 7 | 2 x 7 |

**Appendix G – Fraser Competency Assessment Form**

**Fraser Competency Assessment Form**

For use by Stop Smoking Practitioners when Supplying Nicotine Replacement Therapy to young people aged or appearing to be under 16, when no parent is present at the consulation.

**Please use this form for 13-16 year olds**

The House of Lords in the case of Gillick vs West Norfolk and Wisbech AHA & DHSS in 1985 clarified that young people under the age of 16 can consent to medical treatment if they have sufficient maturity and judgement to enable them fully to understand what is proposed.

It is lawful for health professionals to provide contraceptive advice and treatment without parental consent providing certain criteria are met. These criteria, known as the Fraser Guidelines, were laid down by Lord Fraser in the House of Lords' case and require the professional to be satisfied that:

* The young person will understand the professional's advice
* The young person cannot be persuaded to inform their parents
* The young person is likely to begin, or to continue smoking with or without smoking cessation treatment;
* Unless the young person receives smoking cessation treatment, their physical or mental health, or both, are likely to suffer
* The young person's best interests require them to receive smoking cessation advice or treatment with or without parental consent.

Although these criteria specifically refer to smoking cessation, the principles are deemed to apply to other treatments. If someone under 16 is not judged mature enough to consent to treatment, the consultation itself can still remain confidential.

**Client’s name or identifier:**

**Age:**

**Date of consultation:**

**Signature of professional: Signature of young person:**

**Record of discussion:**

|  |  |
| --- | --- |
| Do you feel that the client understands the advice being given and the potential risks and / or benefits of treatment? |  |
| Will the client agree to involving his/her parents or to allowing you to involve his/her parents? |  |
| What are the likely consequences of not providing smoking cessation treatment? |  |
| Considering the points discussed above, do you consider that it is in the best interests of the client to provide smoking cessation without parental knowledge? |  |
| Please take this opportunity to provide advice on the importance of smoking cessation and protection against smoking related diseases. | |

Attach this to the consultation record and retain securely.