Standard operating procedure for the use of nicotine replacement therapy (NRT) products

Parent Policy / Policies

<table>
<thead>
<tr>
<th>Health and Social Care Act 2012</th>
</tr>
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<tbody>
<tr>
<td>Brighton and Hove Health and Wellbeing Strategy</td>
</tr>
</tbody>
</table>

Links to National Standards, e.g. Care Quality Commission

<table>
<thead>
<tr>
<th>CQC Outcome 4; Care and welfare of people who use services</th>
</tr>
</thead>
<tbody>
<tr>
<td>CQC outcome 9: Management of medicines</td>
</tr>
<tr>
<td>CQC Outcome 12; Requirements relating to workers</td>
</tr>
<tr>
<td>NICE guidance PH10 Stop Smoking Services</td>
</tr>
<tr>
<td>NICE guidance PH26 Smoking: stopping in pregnancy and after childbirth</td>
</tr>
</tbody>
</table>

DATE RATIFIED: 1 September 2016
RATIFIED BY: Stop Smoking Partnership

OWNER: Public Health, Brighton and Hove City Council
AUTHORS: Public Health Tobacco Control and Projects Commissioner and Pharmaceutical Advisor, Brighton & Hove City Council

REVIEW DATE: July 2018
This document remains valid whilst under review

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Changes / Comments</th>
</tr>
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<tbody>
<tr>
<td>1.07.2016</td>
<td>1.1</td>
<td>The original BHCC electronic document is not on file. This SOP was built using the Sussex Community Trust SOP as the basis for the BHCC SOP. Substantial edits and updates have been made to every section to reflect the requirements of BHCC commissioned services. Minor updates include statistical information, website addresses, key contacts and new NRT products.</td>
</tr>
</tbody>
</table>
Appendix B

Contents

<table>
<thead>
<tr>
<th>Summary</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 INTRODUCTION</strong></td>
<td>4</td>
</tr>
<tr>
<td>1.1 Background</td>
<td>4</td>
</tr>
<tr>
<td>1.2 Scope</td>
<td>4</td>
</tr>
<tr>
<td>1.3 Purpose</td>
<td>4</td>
</tr>
<tr>
<td>1.4 Definitions</td>
<td>4</td>
</tr>
<tr>
<td>1.5 Duties of the organisation</td>
<td>4</td>
</tr>
<tr>
<td>1.6 Consultation</td>
<td>5</td>
</tr>
<tr>
<td>1.7 Approval and ratification</td>
<td>5</td>
</tr>
<tr>
<td>1.8 Review</td>
<td>6</td>
</tr>
<tr>
<td>1.9 Equality analysis</td>
<td>6</td>
</tr>
<tr>
<td>1.10 Dissemination plan</td>
<td>6</td>
</tr>
<tr>
<td><strong>2 INDICATION FOR SUPPLY OF NRT PRODUCTS</strong></td>
<td>6</td>
</tr>
<tr>
<td>2.1 Criteria for inclusion</td>
<td>6</td>
</tr>
<tr>
<td>2.2 Criteria for exclusion</td>
<td>6</td>
</tr>
<tr>
<td>2.3 Cautions</td>
<td>7</td>
</tr>
<tr>
<td>2.4 Pregnancy or breast feeding:</td>
<td>7</td>
</tr>
<tr>
<td>2.5 Dosage</td>
<td>8</td>
</tr>
<tr>
<td>2.6 Duration of treatment</td>
<td>8</td>
</tr>
<tr>
<td>2.7 Advice to client (see also individual products in appendix 1)</td>
<td>9</td>
</tr>
<tr>
<td>2.8 Follow up.</td>
<td>10</td>
</tr>
<tr>
<td>2.9 Supply</td>
<td>10</td>
</tr>
<tr>
<td>2.10 Side effects</td>
<td>10</td>
</tr>
<tr>
<td>2.11 Consent</td>
<td>11</td>
</tr>
<tr>
<td>2.12 Record keeping</td>
<td>11</td>
</tr>
<tr>
<td><strong>3 STANDARDS / QUALITY INDICATORS</strong></td>
<td>11</td>
</tr>
<tr>
<td><strong>4 MONITORING COMPLIANCE</strong></td>
<td>12</td>
</tr>
<tr>
<td><strong>5 AWARENESS, TRAINING AND IMPLEMENTATION</strong></td>
<td>12</td>
</tr>
<tr>
<td><strong>6 KEY CONTACTS</strong></td>
<td>12</td>
</tr>
</tbody>
</table>

Appendices:

**Appendix 1** Nicotine replacement therapy product information
- Nicotine medicated chewing gum
- Nicotine inhalation cartridge
- Nicotine lozenges
- Nicotine sublingual tablets
- Nicotine mouth spray
- Nicotine nasal spray
- Nicotine transdermal patch
- Nicotine Oral Strips

**Appendix 2** List of individuals permitted to supply NRT under this SOP
Appendix B

SUMMARY

- This document is for use by all commissioned Brighton & Hove smoking cessation services and the Brighton and Hove City Council health improvement and wellbeing service.

- Provides information for smoking cessation practitioners trained to NCSCT level 2 standard to ensure consistent and appropriate advice and supply of NRT products in line with national guidance.

- Provides guidance for registered healthcare professionals and non-registered healthcare smoking cessation practitioners to support smoking cessation treatment.
1 INTRODUCTION

1.1 Background

Nicotine is a highly addictive substance found in cigarettes\(^1\). Nicotine replacement therapy (NRT) is an effective means of helping people who want to quit smoking overcome cravings of a nicotine addiction. When pharmacotherapy such as NRT is used in conjunction with behavioural support from stop smoking services smokers are four times more likely to stop smoking for good\(^2\).

This standard operating procedure (SOP) enables all trained and supported Stop Smoking Advisors under agreement with Brighton & Hove City Council to be able to advise the supply or supply appropriate NRT products in line with national guidance.

All NRT products have a legal status of General Sales List (GSL) and therefore can be supplied under a SOP. This enables smoking cessation practitioners to advise the supply or supply of appropriate NRT products.

The use of nicotine replacement products in an individual who is already accustomed to nicotine introduces few new risks and it is widely accepted that there are no circumstances in which it is safer to smoke than to use nicotine replacement therapy.

1.2 Scope

This SOP will apply to adolescents 12-17 years and adults (18+) in the Brighton and Hove local authority area and who are deemed appropriate to be assessed for NRT.

1.3 Purpose

This SOP plus appendices provides the criteria under which Stop Smoking Advisors must supply or advise service users regarding NRT.

This SOP supports information issued by National Institute for Health and Clinical Excellence (NICE), National Centre for Smoking Cessation and Training and the electronic Medicines Compendium.

1.4 Definitions

| Nicotine Replacement Therapy (NRT) | Nicotine replacement therapy is the remedial administration of nicotine to the body by means other than tobacco, usually as part of smoking cessation. |

1.5 Duties of the organisation

Stop Smoking Advisors come from a variety of backgrounds and may include registered healthcare professionals and non-registered healthcare professionals.

1.5.1 Responsibilities of the Stop Smoking Advisor:

- Demonstrate competence in delivering stop smoking advice through successful completion of the NCSCT stop smoking practitioner face-to-face training provided by the smoking cessation lead at BSUH and the NCSCT online training assessment for level 1 and level 2.

\(^1\) [http://www.ncsct.co.uk/publication_service_and_delivery_guidance_2014.php](http://www.ncsct.co.uk/publication_service_and_delivery_guidance_2014.php)

\(^2\) [http://www.nhs.uk/smokefree](http://www.nhs.uk/smokefree)
• Act only within and not beyond the boundaries of their knowledge, expertise and/or competence.
• Continue to keep knowledge and skills up to date by continuous professional development (CPD) and attending 2 or 3 update training sessions per year provided by the Smoking Cessation Service Lead (BSUH).
• Undertake/participate in audits of own practice.

1.5.2 Responsibilities of the Line Manager / Clinical Supervisor of registered Stop Smoking Advisors (e.g. practice nurses, pharmacists):

• Ensure that a robust competency framework has been developed and that staff have been assessed against this framework prior to working autonomously with clients.
• Ensure that Advisors act only within and not beyond the boundaries of their knowledge and competence.
• Ensure that Advisors have the opportunity to participate regularly clinical supervision in relation to their duties and that this is documented in their supervision records.
• Ensure that Annual Appraisals are undertaken which includes duties in relation to medicines management, advice and treatment as well as the responsibility towards Health Advisors and their clients.
• Ensure that Advisors adhere to the standard operating procedures outlined in this document and relevant professional codes of conduct in relation to medicines management.

1.5.3 Responsibilities of the Line Manager / Clinical Supervisor of non clinical Stop Smoking Advisors (e.g. Health Care Assistants, Dispensing staff):

• Ensure that a robust competency framework has been developed and that staff members have been assessed against this framework prior to working autonomously with clients.
• Ensure that Advisors act only within and not beyond the boundaries of their knowledge and competence.
• Ensure that Advisors have the opportunity to participate regular supervision and that their duties in relation to the advise and supply of NRT products is part of this process and documented in their supervision records.
• Ensure that Annual Appraisals are undertaken which includes CPD.
• Ensures that Advisors adhere to the standard operating procedures outlined in this document and refer to senior clinicians / Pharmacist any relevant issues in relation to medicines management.

1.6 Consultation

Members of the Stop Smoking Partnership were consulted regarding this SOP. Members include the Director of Public Health (BHCC_, Smoking Cessation lead (BSUH), Commissioner for Primary and Community (CCG), Environmental Health Manager (BHCC), Health Improvement Specialist - Stop Smoking in Schools (SCT), Tobacco Control and Projects Commissioner (BHCC) and Pharmaceutical Advisor (BHCC).

This service is commissioned by Public Health and monitored by a service specification.

1.7 Approval and ratification

The Stop Smoking Partnership is responsible for approving and ratifying this document.
1.8 Review

This document will be reviewed by the Public Health Tobacco Control and Projects Commissioner at least every two years or earlier if appropriate.

1.9 Equality analysis

Brighton and Hove City Council aims to design and implement services, policies & other procedural documents and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

Under the Equality Act 2010, policy or other procedural document authors have a statutory duty to give “due regard” to issues of race, disability, gender (including transgender), religion or belief, age, sexual orientation and human rights when developing their policy or other procedural document. This means that policy or other procedural document authors have to assess the potential for their document to discriminate on any of these grounds. Alternatively, the impact of the policy or other procedural document on these groups might be positive or the same for everyone.

1.10 Dissemination plan

This document will be brought to the attention of all Stop Smoking Advisors and be included as part of the handbook distributed prior to the commencement of a service provider delivering stop smoking services. It will also be available on the Clinic Commissioning Group website and Pharmoutcomes.

2 INDICATION FOR SUPPLY OF NRT PRODUCTS

The following inclusion and exclusion criteria apply to clients receiving advice and support from Brighton & Hove stop smoking services when an aid to treating nicotine dependence is required.

2.1 Criteria for inclusion

- The client is assessed as being nicotine dependent, is still smoking and is sufficiently motivated to quit.
- The client is prepared to comply with nicotine replacement therapy for a minimum period of 10 to 12 weeks. Please note some NRT products are only licensed for a maximum of 12 weeks in young people aged 12-18 (see section 2.5.1)
- The client agrees to receive counselling support in a program agreed between themselves and the smoking cessation practitioner.
- Client consent obtained, or if under 16 years old, has been assessed as Gillick competent. The Gillick competency and Fraser guidelines help us all to balance children’s rights and wishes with our responsibility to keep children safe from harm.

2.2 Criteria for exclusion (also see individual products in Appendix 1)

- Hypersensitivity to nicotine or any of the ingredients in the product
- Not addicted to nicotine
- In hospital as a result of a heart attack
- Current disorders of the heart rate or rhythm
- Stroke / cerebrovascular accident (CVA) within the last 2 weeks

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In the following conditions, NRT products should be used with caution and only in cases where subjects have found it impossible to stop smoking without use of NRT:

- History of stomach ulcer, duodenal ulcer, inflammation of the stomach (gastritis), inflammation of the oesophagitis (passage between the mouth and the stomach) – for oral NRT preparations only
- Insulin controlled diabetes/diabetes mellitus should be advised to monitor blood sugar levels more closely than usual when NRT is initiated as catecholamines released by nicotine can affect carbohydrate metabolism
- Hypertension
- Stable cardiovascular disease
- Unstable/acute asthmatics

**Please note:** Any risks that may be associated with NRT are substantially outweighed by the well-established dangers of continued smoking. However, please refer to pharmacist or general practitioner for guidance when considering issuing NRT for anyone with the following conditions.

### 2.4 Pregnancy or breast feeding:

Pregnant smokers should be encouraged to stop smoking without the use of nicotine replacement therapy products. If this is not possible or unsuccessful then intermittent dosing NRT products may
be preferable to a NRT patch. Avoid liquorice-flavoured nicotine products. However, NRT patches may be preferred if the woman is suffering from nausea during pregnancy. If patches are used they should, if possible, be removed at night when the foetus would not normally be exposed to nicotine.

If breastfeeding, smokers should be given the same advise as with pregnancy. However, were they are unable to stop smoking without using NRT products then the NRT product should be used directly after breastfeeding, to minimise exposure and ensure that the baby gets the smallest amount of nicotine. Mothers should be advised to transfer onto or to begin by using an intermittent dosing NRT product such as gum or inhalator where ever possible.

2.5 Dosage

See individual products in Appendix 1.

2.5.1 Dosage in adolescents (12 to 18 years)

With the majority of NRT products the dose and method of use are as for adults however as data are limited in this age group, the recommended treatment duration is 8 weeks then dose reduction for 4 weeks to give total duration of 12 weeks. It will be important to speak with the adolescent about their preferred medicines for treatment. However based on experience of other stop smoking advisors lozenges, microtablets and inhalers may be more practical. Inhalers may attract attention. Patches may be appropriate for adolescents who smoke 15 or more cigarettes a day.

If treatment is being considered for longer than 12 weeks all clients should be referred to a general practitioner. This should be clearly documented and should only be supported by the stop smoking service or healthcare professional where to do otherwise would result in relapse and then only if the client remains motivated to stop smoking.

Also see individual products in Appendix 1.

2.5.2 Combination therapy

The use of combination therapy (two or more NRT products) should be considered with every client. Two forms of NRT, usually a patch plus a faster acting product, helps to provide a steady dose of nicotine plus a fast acting secondary dose to help with cravings. Using a third product can be useful when a client may not be able to use their preferred NRT products because of restrictions like not being able to chew gum or use an inhalator at work.

NRT can be used in combination with e-cigarettes. Clients of stop smoking services who combined e-cigarettes with behavioural support had the highest quit-rates in 2014–15.

The strength of the products in combination needs to be considered and clients need to be made aware of the symptoms of overdose so that they can manage their medication appropriately. (Overdose usually leads to nausea and removing the patch or taking out the gum will very quickly lead to improvement.)

Under dosing nicotine will reduce efficacy therefore combination therapy is also a very good way of ensuring that a client has enough nicotine not to have withdrawal symptoms.

2.6 Duration of treatment

A maximum of 12 weeks, see individual product details for dose in this period in appendix 1.

4 http://www.ncsct.co.uk/usr/pub/Electronic_cigarettes_A_briefing_for_stop_smoking_services.pdf
Supply under this SOP should be limited to a supported attempt to stop smoking. Maintaining the use of NRT to prevent relapse is exceptional and clients wishing to do so may, at the discretion of the advisor continue with the support of the stop smoking service. However, clients must purchase the NRT supply themselves over the counter or referred to seek support from their own GP. If the client wishes to remain on the NRT longer than 12 weeks, then see individual product details (see also section 2.9.1).

2.7 Advice to client (see also individual products in appendix 1)

2.7.1 Written advice

Manufacturer’s patient information leaflet (PIL) must be issued and explained to all clients. Clients should be advised to read the leaflet and to raise any queries with the Stop Smoking Adviser or relevant healthcare professional (e.g. doctor, nurse or pharmacist).

2.7.2 Additional advice

- Withdrawal symptoms.
- Possible changes to the body on stopping smoking and how to manage them e.g. weight gain.
- Effects of smoking tobacco whilst using NRT (particularly in vulnerable groups such as pregnant women).
- Correct way to use medication in order to gain best effect, e.g. how to apply a patch, position and use of the mouth spray.
- Acidic beverages, such as coffee or fruit juice, may decrease the absorption of nicotine through the mouth and should be avoided for 15 minutes before the use of oral NRT.
- Follow up and obtaining further supplies of NRT.
- Potential side effects and adverse reactions of NRT and how to manage these, including when it may be necessary to seek medical advice and or cease treatment. This should include that exercise may increase absorption and side-effects.
- Storage conditions and disposal.
- Keep out of reach and sight of children.
- Danger in small children: Doses of nicotine tolerated by adult and adolescent smokers can produce severe toxicity in small children that may be fatal. Products containing nicotine should not be left where they may be misused, handled or ingested by children.
- Clients should always be directed to the patient information leaflet (PIL) supplied with the NRT product, for up to date information relating to dosage, side-effects and storage of the product.
- Information about where to obtain further advice:
  Smoking Cessation Lead (BSUH) 01273696955 extension 7445
  General advice on stopping smoking: 0300 123 1044 (National Helpline).
  General information on local stop smoking services https://www.brighton-hove.gov.uk/content/health/stop-smoking.
2.8 Follow up.

As agreed in care planning process. Minimum of 4 weeks after quit date.
Carbon monoxide monitoring at 4 week review as a minimum to confirm abstinence from smoking at four weeks following the quit date.

2.9 Supply

2.9.1 Maximum quantity to be supplied

Maximum 2 weeks supply at any one time during weeks 1 to 4 (exceptions are holidays, or person unable to attend next session) and then NRT can be supplied for up to 4 weeks at a time. Supply should only be made in the appropriate original pack.

The table below should be used as a guide to frequency of issue of NRT

<table>
<thead>
<tr>
<th>Session</th>
<th>NRT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 1 Initial Assessment</td>
<td>2 weeks supply of NRT (Including combination therapy)</td>
</tr>
<tr>
<td>Session 2 Quit date</td>
<td>No medication normally required</td>
</tr>
<tr>
<td>Session 3 Post-quit - week 1</td>
<td>2 weeks supply of NRT (Including combination therapy)</td>
</tr>
<tr>
<td>Session 4 Post-quit - week 2</td>
<td>No medication normally required</td>
</tr>
<tr>
<td>Session 5 Post-quit – week 3</td>
<td>2 weeks supply of NRT (Including combination therapy)</td>
</tr>
<tr>
<td>Session 6 4 week quit appointment – post quit – week 4</td>
<td>4-6 weeks supply of NRT (Including combination therapy)</td>
</tr>
<tr>
<td></td>
<td>Total amount of medication: 12 weeks supply (per product)</td>
</tr>
</tbody>
</table>

2.10 Side effects

Some of the side effects are detailed below and in the individual product details in the appendix 1. “Very common” side effects are when more than 1 in 10 people may be affected, “common” side effects are when less than 1 in 10 people but more than 1 in 100 people may be affected. For a full list of side effects or further information see the Summary of product characteristics (SPC) or PIL provided with the product.

Some symptoms may be related to nicotine withdrawal associated with stopping smoking. These can include; malaise, headache, dizziness, coughing, influenza-like symptoms, depression, irritability, restlessness, increased appetite/weight gain, urges to smoke (cravings), sleep disturbance, palpitations and decreased heart rate. Gastro-intestinal disturbances are common, and may be caused by swallowed nicotine. Nausea, vomiting, indigestion and hiccup occur most frequently. Mouth ulcers have also been reported.

NRT may cause adverse reactions similar to those associated with nicotine given by other means, including smoking, and these are mainly dose dependent. At recommended doses NRT has not been found to cause any serious adverse effects.

Excessive use of NRT by those who have not been in the habit of inhaling tobacco smoke could possibly lead to nausea, faintness or headaches.
2.10.1 Untoward events and adverse drug reactions

In the case of a severe reaction call 999.

A client presenting with a suspected Adverse Drug Reaction (ADR) should be referred to a healthcare professional for further investigation. Consent should be obtained from the client before passing details of the adverse reaction to the clients GP.

For further information regarding drug interactions refer to: Summary of Product Characteristics (SPC) & British National Formulary (BNF). Also see NeLM QA 136-3 Smoking and Drug Interactions

All serious side effects that have been or are suspected of being caused should be reported on the Yellow Card Scheme – available at the back of the BNF or at https://yellowcard.mhra.gov.uk/

2.11 Consent

Clients must give informed consent to the use of NRT products as part of treatment which must include accessing appropriate support from stop smoking services. Clients must be able to give consent in accordance with the Mental Capacity Act 2005 (MCA)

2.11.1 Action if client declines treatment

Offer alternative support / refer to alternative healthcare professional if necessary, and document the advice given.

2.12 Record keeping

Records should comply with the appropriate Records Management Procedure. They should always include:

- Date of consultation and supply.
- Client name, address, date of birth.
- GP details where possible.
- Dose, quantity and form of NRT advised for supply or supplied.
- Consent obtained at commencement of treatment
- Gillick competency assessment undertaken for 12-16 years of age.
- Advice given to client.
- Name of medicine and manufacturer or brand name.
- Batch number and expiry date (optional).
- Member of staff who supplied the medication and designation (HCA, nurse, pharmacist, pharmacy technician).
- Directions provided to the client e.g. Patient Information Leaflet
- Details of any adverse drug reaction and actions taken are recorded and client informed to advise their general practitioner.
- Completion of Stop Smoking clinic documentation as appropriate.

A record of the consultation should be kept for 2 years after the client’s last attendance or until the clients 26th birthday if longer than 2 years away. This applies unless there is a clinical indication to keep longer.

3 STANDARDS / QUALITY INDICATORS

Audit of work against the SOP should be carried out each year by providers of stop smoking services. Exceptions should be reported to the Public Health Tobacco Control and Projects

Commissioner. The content and timing of the audit should reflect current service and organisational needs.

The annual audit of the paperwork used to record the use of NRT should be undertaken in addition to any others such as list of Stop Smoking Advisors permitted to supply or advise the supply NRT under this SOP in Appendix 2. This audit should be looking for evidence of adherence to the NRT SOP.

In addition providers must ensure Stop Smoking Advisor’s maintain their level of competency (refer section 5).

4 MONITORING COMPLIANCE

Compliance will be monitored by:

- The review of incident reports by the Public Health Tobacco Control and Projects Commissioner in accordance with local commissioned services contracts in order to identify local problems, key risks, trends and recommend mechanisms to prevent re-occurrence.

- Audit results should be reported by exception only to the Public Health Tobacco Control and Projects Commissioner (BHCC) annually.

5 AWARENESS, TRAINING AND IMPLEMENTATION

Stop Smoking Advisors working under an agreement with the Brighton and Hove City Council must demonstrate competence as a stop smoking practitioner through the NCSCT level 2 stop smoking practitioner face-to-face training delivered by the Smoking Cessation Service Lead (BSUH) and NCSCT online assessment. Records of completing the online assessment must be submitted to the Smoking Cessation Lead (BSUH) within the first year of delivering the service.

In addition Stop Smoking Advisors must attend regular update events (at least two of the three events per year). Any Stop Smoking Advisors who have not delivered a stop smoking clinic for over one year must attend a refresher level 2 Smoking Cessation Practitioner training facilitated by the Smoking Cessation lead.

6 KEY CONTACTS

<table>
<thead>
<tr>
<th>Position</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking Cessation Lead (BSUH)</td>
<td><a href="mailto:anna.fairhurst@bsuh.nhs.uk">anna.fairhurst@bsuh.nhs.uk</a></td>
<td>01273 696955 x7445</td>
</tr>
<tr>
<td>Public Health Tobacco Control and Projects Commissioner</td>
<td><a href="mailto:Susan.stewart@brighton-hove.gov.uk">Susan.stewart@brighton-hove.gov.uk</a></td>
<td>01273 293927</td>
</tr>
<tr>
<td>Pharmacy Advisor</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 1: Nicotine replacement therapy (NRT) product information
(This information is in addition to the information in the main SOP)

Advice to supply or supply of nicotine medicated chewing gum (Niquitin®, Nicorette®, Nicotinell®)

<table>
<thead>
<tr>
<th>Name, form and strength of medicine to be supplied</th>
<th>Niquitin® chewing gum 4 mg and 2mg. Nicorette® chewing gum 6mg, 4 mg and 2mg. Nicotinell® chewing gum 4mg and 2mg.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route / method</td>
<td>Oral medicated chewing gum.</td>
</tr>
<tr>
<td>Dosage</td>
<td>One piece of gum to be chewed when the client feels the urge to smoke.</td>
</tr>
<tr>
<td></td>
<td>Individuals who smoke fewer than 20 cigarettes each day should use one piece of 2mg strength gum; individuals who smoke more than 20 cigarettes each day or who require more than 15 pieces of 2mg strength gum each day should use the 4mg or 6mg strength. The 6mg gum can be recommended particularly to those requiring enhanced craving relief compared to 4mg gum.</td>
</tr>
<tr>
<td></td>
<td>Normally, 8 – 12 pieces per day to be used, up to a maximum of 15 pieces per day (24 hour period). <strong>This applies to all strengths of gum.</strong></td>
</tr>
<tr>
<td></td>
<td>Lower dosage gum may also be helpful during withdrawal from the higher dose gum.</td>
</tr>
<tr>
<td></td>
<td>Clients who report an adverse event from using the higher dosage gum should be encouraged to replace it with the lower dosage form.</td>
</tr>
<tr>
<td></td>
<td>Clients who are also using another NRT product (in combination therapy) should be encouraged to use as above but should then reduce from 4 mg to 2 mg gum if there are any adverse events.</td>
</tr>
<tr>
<td></td>
<td>Concomitant use of acidic beverages such as coffee or soda may decrease the buccal absorption of nicotine. Acidic beverages should be avoided for 15 minutes prior to chewing the gum.</td>
</tr>
<tr>
<td>Treatment details</td>
<td>Adults (over 18 years of age)</td>
</tr>
<tr>
<td></td>
<td>The chewing gums should be used whenever there is an urge to smoke according to the &quot;chew and rest&quot; technique. Absorption of nicotine is through the lining of the mouth (buccal mucosa); any nicotine which is swallowed is destroyed by the liver.</td>
</tr>
<tr>
<td></td>
<td>After about 30 minutes of such use, the gum will be exhausted.</td>
</tr>
<tr>
<td></td>
<td>The treatment time is individual. Treatment should continue for an initial period of 10 weeks. Clients who have successfully abstained from smoking during this 10 week period should be supported through a further 2 week weaning period, using lower strength gum.</td>
</tr>
<tr>
<td></td>
<td>For Niquitin® if a reduction in cigarette consumption has not been achieved after 6 weeks of treatment, the manufacturer recommends a healthcare professional should be consulted.</td>
</tr>
<tr>
<td></td>
<td>The manufacturer recommends that adults who use NRT beyond 6 months (for Niquitin®) or 9 months (for other products) are recommended to seek additional help and advice from a healthcare professional.</td>
</tr>
<tr>
<td></td>
<td><strong>Adolescents (12 to 18 years):</strong></td>
</tr>
<tr>
<td></td>
<td>See section 2.5. For Niquitin® and Nicorette® the manufacturer recommends that adolescents (12 to 17 years) should follow the above usage advice. The manufacturer of Nicotinell® recommend that medical advice should be obtained should it be found necessary to use the gum beyond 12 weeks. Nicorette 6mg gum is contraindicated in children under the age of 12 years.</td>
</tr>
<tr>
<td>Exclusions</td>
<td>Pregnancy and lactation: Use of gum with liquorice (glycyrrhizin) is</td>
</tr>
</tbody>
</table>
contraindicated in pregnancy and lactation.

Clients with fructose intolerance should not use NRT gum.

Clients on a sodium restricted diet - Some products contains sodium check the patient information leaflet supplied with the product.

Clients on Anti-epilepsy drugs (AEDs) or with a history of epilepsy.

| Side effects | Excessive swallowing of dissolved nicotine may, at first, cause hiccupping. Nicotine from the gum may sometimes cause irritation of the throat at the start of treatment and may also cause increased salivation. Those who are prone to indigestion may suffer initially from minor degrees of indigestion or heartburn if 4 mg gum is used; slower chewing and the use of 2mg nicotine gum (if necessary more frequently) will usually overcome this problem.

Denture warning: NRT gum may stick to, and in rare cases damage dentures.

Some products contain sodium, which should be taken into consideration by patients on a controlled sodium diet.

Some products contain butylated hydroxy toluene (E321); this may cause irritation to the mucous membranes.

Those who experience excessive side effects with the 6mg gum, should discard the gum and increase the period of time taken between each gum. If side-effects do not resolve then individuals should switch to the 4mg gum.

Some of the more common side effects are listed below:

**Very common:**
Sore mouth or throat, jaw-muscle ache, increased salivation, headache, stomach discomfort, hiccups, feeling sick (nausea), cough, throat irritation.

**Common side-effects:**
Dizziness, sickness (vomiting), oral soft tissue pain, paraesthesia and jaw muscle ache, abdominal pain, dry mouth. Refer to the product SPC and PIL for the full list.

<table>
<thead>
<tr>
<th>REFERENCES</th>
</tr>
</thead>
</table>
Advice to supply or supply of nicotine inhalation cartridge (Nicorette® Inhalator 15mg)

<table>
<thead>
<tr>
<th>Name, form and strength of medicine available to be supplied</th>
<th>Nicorette® Inhalator (15mg per cartridge).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route / method</td>
<td>Inhalation cartridge for oromucosal use.</td>
</tr>
<tr>
<td>Dosage</td>
<td>A cartridge can be used when the urge to smoke occurs or to prevent cravings.</td>
</tr>
<tr>
<td></td>
<td><strong>15mg cartridge:</strong> Each cartridge can be used for approximately 8 five minute sessions, with each cartridge lasting approximately 40 minutes of intense use. Maximum daily dose (24 hour period) of 6 cartridges.</td>
</tr>
<tr>
<td>Treatment details</td>
<td>The cartridge is inserted into the device mouthpiece according to the instructions. When a client draws air into the mouth through the mouthpiece, nicotine is vaporised and absorbed by the buccal mucosa. 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.</td>
</tr>
<tr>
<td></td>
<td>If the client has a long term throat disease or difficulty breathing due to bronchitis, emphysema or asthma Nicorette® inhalator may not be suitable and another NRT product may be preferred.</td>
</tr>
<tr>
<td></td>
<td>Once inserted into the mouthpiece the cartridge should be disposed of within 48 hours even if it has not been used.</td>
</tr>
<tr>
<td></td>
<td>Potential choking hazard: This product contains some small parts. Any unused cartridges should remain in the cartridge tray to minimise the risk of swallowing.</td>
</tr>
<tr>
<td></td>
<td><strong>Adults and Adolescents (12 to 18 years):</strong> Treatment should continue on a daily basis for an initial period of 8 weeks*. Clients who have successfully abstained from smoking during this 8 week period should be supported through a further 4 week weaning period.</td>
</tr>
<tr>
<td></td>
<td>*8 week duration is acceptable common practice.</td>
</tr>
<tr>
<td></td>
<td><strong>Adolescents (12 to 18 years):</strong> Refer Adolescents to their GP if they require a course of treatment of more 12 weeks. See section 2.5.1</td>
</tr>
<tr>
<td>Side effects</td>
<td>About 40% of Nicorette® inhalator users experience mild local reactions such as cough and irritation in the mouth and throat.</td>
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<tr>
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<td>Some of the side effects are detailed below:</td>
</tr>
<tr>
<td></td>
<td><strong>Very common side-effects:</strong></td>
</tr>
<tr>
<td></td>
<td>• Headache.</td>
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<tr>
<td></td>
<td>• Cough.</td>
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<td></td>
<td>• Irritation of the mouth, nose or throat.</td>
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<td></td>
<td><strong>Common side-effects:</strong></td>
</tr>
<tr>
<td></td>
<td>• Dizziness.</td>
</tr>
<tr>
<td></td>
<td>• Nasal congestion.</td>
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<tr>
<td></td>
<td>• Stomach discomfort.</td>
</tr>
</tbody>
</table>
|                                                            | • Hiccups.
Feeling sick (nausea).
Sickness (vomiting).

References

Advice to supply or supply of nicotine lozenges (NiQuitin® Nicotinell®)

<table>
<thead>
<tr>
<th>Name, form and strength of medicine available to be supplied</th>
<th>NiQuitin® lozenge 4 mg, 2 mg. NiQuitin® mini lozenge 4 mg and 1.5mg Nicotinell® lozenge 2mg and 1mg.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route / method</td>
<td>Oral lozenge.</td>
</tr>
<tr>
<td>Dosage</td>
<td>Dosage depends on the level of nicotine dependence of the client. Individuals who smoke less than 20 cigarettes each day should use the lower strength lozenges (i.e. 1mg or 1.5mg lozenge should be considered); individuals who smoke more than 20 cigarettes each day or those or have a moderate to very strong dependence then the 2 mg or 4 mg lozenge should be considered. Initially one lozenge should be used every 1 to 2 hours when the urge to smoke occurs. Maximum daily dose of 15 lozenges per day.</td>
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<tr>
<td>Treatment details</td>
<td>The lozenge should be slowly allowed to dissolve in the mouth; periodically move the lozenge from one side of the mouth to the other. Lozenges last for 10 to 30 minutes, depending on their size. The lozenge should not be chewed or swallowed whole. Users should not eat or drink while a lozenge is in the mouth.</td>
</tr>
<tr>
<td>Adults (over 18 years of age):</td>
<td>Following the initial dose, after 6 weeks a decision to ‘step down’ treatment can be made and the frequency of taking a lozenge should move to every 2 – 4 hours for 3 weeks and then every 4 – 8 hours for 3 weeks. The manufacturers state that adults who use NRT beyond 6 months (for NiQuitin®) and 9 months (for Nicotinell®) are recommended to seek additional help and advice from a healthcare professional.</td>
</tr>
</tbody>
</table>
| Adolescents (12 to 18 years):                               | - For NiQuitin® the manufacturer recommends that adolescents (12-17 years) should follow the schedule of treatment for abrupt cessation of smoking as given above. Where adolescents are unwilling or unable to quit smoking abruptly, advice from a healthcare professional should be sought.  
- For Nicotinell® the manufacturer states this should not be used by people under 18 years of age without recommendation from a physician. |
| Exclusion                                                   | Hereditary conditions of fructose intolerance - may contain maltitol (E965), a source of fructose. Clients with rare hereditary conditions of fructose intolerance should not take any brand / flavour containing maltitol.  
Clients taking anti-epileptic drugs (AEDs) or with a history of epilepsy. |
| Cautions:                                                   | Care needs to be taken in the following situations, dependent on which brand / flavour of lozenge is being used:  
- Phenylketonuria – may contain a source of phenylalanine which may be harmful for people with phenylketonuria.  
- Restricted sodium - may contain sodium, people on a low sodium diet should... |
prior to supplying NRT
take this into account.

Side effects
Some of the side effects are detailed below:

**Very Common:**
- Feeling sick.
- Increased salivation.

**Common side effects:**
- Sore throat.
- Dry mouth
- Being sick.
- Stomach discomfort (dyspepsia, heartburn, indigestion).
- Diarrhoea.
- Constipation.
- Bloating.
- Flatulence.
- Hiccups.
- Insomnia; anxiety; irritability; increased appetite.
- Headache.
- Mouth irritation, mouth ulceration; tongue ulceration.

See the Summary of Product Characteristics (SPC) for the full list of side effects.

References

Advice to supply or supply of nicotine sublingual tablets (Nicorette® Microtabs)

<table>
<thead>
<tr>
<th>Name, form and strength of medicine available to be supplied</th>
<th>Nicorette® Microtab, 2 mg.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route / method</td>
<td>Sublingual tablet.</td>
</tr>
<tr>
<td>Dosage</td>
<td>The initial dose is based on an individual’s nicotine dependence. Each tablet should be placed under the tongue and allowed to dissolve. The recommended dose is one tablet per hour or, for heavy smokers (smoking more than 20 cigarettes per day), two tablets per hour. Increasing to two tablets per hour may be considered for clients who fail to stop smoking with one tablet per hour regimen or for those at risk of relapse. Most smokers require 8 to 12 or 16 to 24 tablets in one 24 hour period. Not more than 40 tablets in a 24 hour period should be used.</td>
</tr>
<tr>
<td>Treatment details</td>
<td>Adults (over 18 years of age): Daily treatment commences as described above. Treatment should continue at this dose on a daily basis for an initial period of 8 weeks*. Clients who have successfully abstained from smoking during this 8 week period should be supported through a further 4 week weaning period. Treatment should end when daily consumption is down to one or two tablets.</td>
</tr>
</tbody>
</table>
The manufacturer recommends that adults who use NRT beyond 9 months are recommended to seek additional help and advice from a healthcare professional. *8 week duration is acceptable common practice.

**Adolescents (12 to 18 years):**
See section 2.5.

### Side effects

Some of the common side effects include:
- Dizziness.
- Headache.
- Palpitations.
- Coughing.
- Gastrointestinal discomfort, nausea.
- Hiccups.
- Sore mouth or throat, dry mouth, burning sensation in the mouth.
- Rhinitis.

### References


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### Advice to supply or supply of nicotine mouth spray (Nicorette® Quickmist)

<table>
<thead>
<tr>
<th>Name, form and strength of medicine available to be supplied</th>
<th>Nicorette® QuickMist (mouth spray) 1mg per spray.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route / method</td>
<td>Mouth (oromucosal) spray.</td>
</tr>
<tr>
<td>Dosage</td>
<td>Point the spray nozzle as close to the open mouth as possible. Press the top of the dispenser and release one spray into the mouth, avoiding the lips and avoiding inhaling the spray. 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. Smokers 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.</td>
</tr>
<tr>
<td>Treatment details</td>
<td>Adults and children over 12 years of age: The manufacturer recommends that those who have quit smoking but are having difficulties discontinuing their mouth spray are recommended to contact their pharmacist or doctor for advice. If that client is in contact with the Stop Smoking Service or healthcare professional it is appropriate for a trained stop smoking advisor to give advice and support to help discontinue use of the mouth spray. Referral to the GP or pharmacist should take place if the client does not wish to continue contact with the stop smoking service / healthcare professional or if there are additional health care needs.</td>
</tr>
</tbody>
</table>
| Additional information | • Contains ethanol (less than 100 mg of ethanol per spray dose).
• If using Nicorette® QuickMist for the first time or if not used the spray for 2 days, the spray pump must be primed.
• Do not inhale while spraying to avoid getting spray down the throat. |

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Date ratified: 09.07.2014
- Care should be taken not to spray the eyes whilst administering the mouth spray.
- The patient should not eat or drink when administering the oromucosal spray.

### Side effects

During the first few days of treatment watery eyes and blurred vision may occur. Some of the side effects are detailed below:

**Very Common:**
- Throat and mouth irritation / pain.
- A change in the way things taste.
- Headache.
- Feeling sick (nausea), indigestion.
- Increased salivation.
- Burning lips.
- Dry mouth / throat.
- Hiccups.
- Tingling sensation in the mouth.
- Inflammation of the lining of the mouth.

**Common side effects:**
- Dizziness.
- Tingling sensation (pins and needles).
- Vomiting.
- Abdominal pain.
- Diarrhoea.
- Throat tightness.
- Tiredness.
- Chest pain and discomfort.
- Toothache.
- Flatulence.

### References

  Available at [http://www.medicines.org.uk/EMC/medicine/24257/SPC/Nicorette+QuickMist+1mg+spray+mouthspray/](http://www.medicines.org.uk/EMC/medicine/24257/SPC/Nicorette+QuickMist+1mg+spray+mouthspray/)

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### Advice to supply or supply of nicotine nasal spray (Nicorette®)

#### Name, form and strength of medicine available to be supplied

- Nicorette® Nasal Spray.
- Nicotine 10 mg per ml solution. Each spray delivers 0.5 mg nicotine.

#### Route / method

- Nasal spray.

#### Dosage

- The frequency of use depends on the previous smoking habit of the individual and their level of nicotine dependence. Clients can use 1 spray in each nostril when the urge to smoke occurs, subject to a limit of one spray to each nostril twice an hour.
  - 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.

#### Treatment details

- The spray should be primed before use for the first time.
  - **Adults (over 18 years of age):**
    - Daily treatment commences with clients using the spray as instructed as required.
    - Treatment should continue for an initial period of 8 weeks. After this period the client reduces usage until after 4 more weeks treatment has ended. This can be
achieved by halving use after 2 weeks and then achieving zero use after 4 weeks. When withdrawing from therapy, the dose can be reduced by using one spray in one nostril.

The manufacturer recommends that adults who use NRT beyond 9 months are recommended to seek additional help and advice from a healthcare professional.

**Adolescents (12 to 18 years):**

See section 2.5. The dose and method of use are as for adults however as data are limited in this age group, the recommended treatment duration is 12 weeks. If longer treatment is required, advice from a healthcare professional should be sought.

**Exclusions**

**Asthma:** Exacerbation of bronchospasm in clients with bronchial asthma has been reported. Use of the spray in clients with hyper-reactive airways is not recommended.

**Further information**

- The nasal spray should not be used whilst the user is driving or operating machinery as sneezing and watering eyes could contribute to accidents.
- **Allergic reaction:** Nicorette® Nasal Spray contains methyl- and propyl-hydroxybenzoates (E217 and E218) which may cause allergic reactions (possibly delayed). Clients should be informed of this possibility and given clear instructions of what to do should they experience an allergic reaction.

**Side effects**

During the first 2 days of treatment, nasal irritation as sneezing, running nose, watering eyes, cough was reported by nearly all (94%) of the clients. Both the frequency and severity declined with continued use.

Some of the side effects are detailed below:

**Very Common:**

- Epistaxis.
- Running nose.
- Sneezing.
- Watering eyes.

**Common side effects:**

- Dizziness.
- Headache.
- Coughing.
- Gastrointestinal discomfort, nausea, vomiting.

**References**


Advice to supply or supply of nicotine transdermal patch (Nicorette®, Nicotinell®, NiQuitin®)

**Name, form and strength of medicine available to be supplied**

- Nicorette® Invisi 16 hour patch 25mg, 15mg and 10mg.
- Nicotinell® TTS 24 hour patch 21mg, 14mg and 7mg.
- NiQuitin® 24 hour patch 21mg, 14mg and 7mg.

**Route / method**

Transdermal patch.

**Dosage**

The patch should be worn continuously, either for 24 hours for the 24 hour patch or for a 16 hour period in a 24 hour period in the case of 16 hour patches.

A patch should be applied preferably on waking to dry, non-hairy skin on the hip, truck, or uppermost arm and held in position for 10 to 20 seconds to ensure
proper adhesion of the patch. After 16 or 24 hours (depending on the patch) the used patch should be removed and a new patch applied to a fresh skin site. The patch should not be left on for longer than the specified 16 or 24 hour period. Skin sites should not be reused for at least seven days. Only one patch should be worn at a time.

Clients who smoke more than 10 cigarettes a day should apply a high-strength patch daily initially; Clients who smoke fewer than 10 cigarettes daily can usually start with the medium strength patch daily. The strength of patch being used can be to be reduced as detailed in the treatment details section.

### Treatment details

**Adults (over 18 years of age):**

Treatment should continue at the recommended dose on a daily basis for an initial period of 8 weeks. Clients who have successfully abstained from smoking during this 8 week period should be supported through a further 4 week weaning period, using lower strength patches. Downwards titration of dose is usually achieved by applying one lower strength patch from the same range patch daily for 2 weeks followed by the lowest strength patch from that same range daily for a further 2 weeks.

The manufacturers recommend that adults who use NRT beyond 6 to 9 months are recommended to seek additional help and advice from a healthcare professional.

**Adolescents (12 to 18 years):**

See section 2.5.

For NiQuitin® the manufacturers recommend that adolescents (12 to 17 years) should follow the schedule of treatment for abrupt cessation of smoking as given above. Where adolescents are not ready or not able to stop smoking abruptly, advice from a healthcare professional should be sought.

### Exclusions

- Generalised dermatological disorders as the disease may complicate patch therapy: Clients with chronic generalised dermatological disorders such as psoriasis, chronic dermatitis or urticaria should not use NRT patch.
- Clients taking anti-epileptic drugs (AEDs) or with a history of epilepsy.

### Further information

- **Pregnancy:** patches may be preferred if the woman is suffering from nausea during pregnancy. **Where a patch is used then it should be removed before going to bed** when the foetus would not normally be exposed to nicotine.
- The dosage must not be adjusted by cutting a patch.
- The patch will normally resist bathing, showering, or swimming, but if it does come off it should be replaced with a new one. Use of skin oils or talc can prevent proper adhesion of the patch.
- Safety on handling: NiQuitin is potentially a dermal irritant and can cause contact sensitisation. Care should be taken during handling and in particular contact with the eyes and nose avoided. After handling, wash hands with water alone as soap may increase nicotine absorption.
- Avoid applying to any skin which is broken, red or irritated, or to anyone with a skin disorder.
- **Atopic or eczematous dermatitis (due to localised patch sensitivity):** In the case of severe or persistent local reactions at the site of application (e.g. severe erythema, pruritus or oedema) or a generalised skin reaction (e.g. urticaria, hives or generalised skin rashes), users should be instructed to discontinue use of the patch and contact their physician.

### Side effects

About 20% of NRT patch users experience mild local skin reactions, during the first weeks of treatment. In some clients the skin reactions may become more severe e.g. skin blistering or a burning sensation or may be more generalized.
Some of the side effects are detailed below:

**Very Common:**
- Sleep disorders including abnormal dreams and insomnia.
- Dizziness.
- Headache.
- Nausea, vomiting, gastrointestinal discomfort.
- Application site reactions.
- Itching.

**Common side effects:**
- Nervousness.
- Tremor.
- Palpitations.
- Dyspnoea, pharyngitis, cough.
- Dyspepsia, abdominal pain upper, diarrhoea NOS, dry mouth, constipation.
- Increased sweating.
- Arthralgia, myalgia.
- Chest pain, pain in limb, pain NOS, asthenia, fatigue.

**References**

**Advice to supply or supply of Niquitin (oral) strips.**

| Name, form and strength of medicine available to be supplied | Niquitin Strips (mint) 2.5mg (30)  
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Niquitin Strips (mint) 2.5mg (60)</td>
<td></td>
</tr>
<tr>
<td><strong>Route / method</strong></td>
<td>Orodispersible Film</td>
</tr>
<tr>
<td><strong>Dosage</strong></td>
<td>Adults and children over 12 years (abrupt cessation guidance). Suitable for smokers who have their first cigarette of the day more than 30 minutes after waking up. The number of films per day is variable and depends on the patient’s needs. Nonetheless it should not exceed 15 films per day.</td>
</tr>
<tr>
<td><strong>Treatment details</strong></td>
<td>Place one film on the tongue. Close the mouth and press the tongue gently to the roof of the mouth until the nicotine film dissolves (approximately 3 minutes). The film should not be chewed or swallowed whole. Users should not eat or drink while a nicotine film is in the mouth.</td>
</tr>
</tbody>
</table>
| **Exclusions** | People with a hypersensitivity to nicotine or any of the excipients  
| | Children under the age of 12 years  
| | Non-smokers |
| **Further information** | This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per nicotine film.  
| | This product is indicated in pregnant and lactating women making a quit attempt |
Nicotine may possibly enhance the haemodynamic effects of adenosine.

<table>
<thead>
<tr>
<th>Side effects</th>
<th>Very Common nausea</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Common insomnia, headache, dizziness, pharyngitis, cough, vomiting, dyspepsia, abdominal pain upper, diarrhoea, dry mouth, constipation, hiccups, stomatitis, flatulence, oral discomfort. Refer to the SPC or PIL for the full list.</td>
</tr>
</tbody>
</table>

| References     | NiQuitin Strips 2.5mg Oral Film Specific Product Characteristics Accessed 27/6/16 [https://www.medicines.org.uk/emc/medicine/27614/SPC/NiQuitin+Strips+2.5mg+Oral+Film/](https://www.medicines.org.uk/emc/medicine/27614/SPC/NiQuitin+Strips+2.5mg+Oral+Film/) |
Appendix 2: List of individuals permitted to supply or advise the supply of NRT under this SOP

1. The individuals listed below have received the appropriate training and are permitted to supply or advise the supply of NRT products for clients of the Stop Smoking Service.
2. Individuals listed below must also have read, understood and signed the relevant SOP and appendices in order to supply or advise the supply of NRT.
3. This list is to be kept on file by each provider organisation and referenced as part of the annual audit of NRT (refer to section 3)

Name or Manager:

Signature of Manager:  
Date:

<table>
<thead>
<tr>
<th>Names of individuals permitted to supply or advise the supply of NRT products under this SOP</th>
<th>Signature of individual</th>
<th>Work Base</th>
<th>Signature of Manager</th>
<th>Date</th>
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