

## **Cut Down with Nicorette (nicotine) then Stop Backgrounder**

### **What is Cut Down with Nicorette then Stop?**

*Cut Down with Nicorette then Stop* completely is the new four step approach to smoking cessation from Nicorette for those smokers who cannot stop abruptly. It is based on smoker understanding and clinical evidence, with the ultimate goal of stopping smoking completely within six to nine months. The four step approach is as follows:

#### **Step 1:** (0-6 weeks) – START CUTTING DOWN

- Smoker sets target for both the number of cigarettes per day to cut down and a date to achieve it by. (Recommend at least a 50% reduction for best results)
- Advise smoker to use Nicorette Gum or Inhalator as required to manage cravings
- Advise smoker to return if not cut down within six weeks

#### **Step 2:** (6 weeks up to 6 months) – CONTINUE CUTTING DOWN

- Smoker continues to cut down cigarettes using Nicorette Gum or Inhalator
- Goal should be to complete stop by 6 months
- Advise smoker to return if not managed to stop smoking within 9 months

#### **Step 3:** (within 9 months) – STOP SMOKING

- Smoker stops all cigarettes and continues to use Nicorette Gum or Inhalator to relieve cravings

#### **Step 4:** (within 12 months) – STOP NICORETTE

- Use of Nicorette Gum or Inhalator is gradually cut down, then stopped completely (within 3 months of stopping smoking)

### **The importance of *Cut Down with Nicorette then Stop***

The main focus of the public health community is to discourage people from starting to smoke and to encourage current smokers to give up. Although most smokers (50 - 70%) are unhappy with their smoking<sup>1,2</sup>, many never actually try and long-term success rates are modest. But, for every two smokers who do give up, one premature death will be prevented<sup>3</sup>. The Government and other bodies including NICE have called for new strategies to help more smokers stop.<sup>4-6</sup> To date, NRT has been licensed only for smokers that are able to stop abruptly.

With this in mind, *Cut Down with Nicorette then Stop* completely has been developed to engage a further 4 million smokers who are not able or ready to give up abruptly but want to change their smoking<sup>2</sup>. They may be ready to reduce the amount they smoke as a first step to being smoke-free<sup>1,7</sup>

The new indication for Nicorette Gum and Inhalator helps such smokers to stop by helping them cut down the number of cigarettes they smoke before stopping completely. By cutting down, smokers may then gain confidence in their ability to do without cigarettes and be able to choose a stop date that is achievable for them.

A recent Cochrane Review of NRT in Smoking Cessation advises that using NRT doubles a person's chance of giving up successfully<sup>8</sup>. *Cut Down with Nicorette then Stop* completely has potential benefits for both the individual smoker and the health service, engaging many more smokers who can't stop using current abrupt

methods and providing an opportunity to stop by using a different approach. As smoking reduction can increase cessation, *Cut Down with Nicorette then Stop* may benefit public health by reducing the incidence of tobacco-related cardiac and respiratory disease, and ultimately relieve pressure on provision of health services.

## Data

### Efficacy

*Cut Down with Nicorette then Stop* has been clinically proven to significantly increase the chance of successful smoking reduction *and* ultimate cessation, compared to placebo or willpower alone<sup>9</sup>. Trial selection criteria specified being unable or unwilling to stop smoking but, following the trials, intention to give up was improved in 55 - 80% of participants<sup>10</sup>, and one in three smokers who successfully cut down by half with Nicorette had stopped smoking within one year.<sup>9</sup>

Further evidence from the *Cut Down with Nicorette then Stop* clinical trials programme also suggests that a reduction in the number of cigarettes smoked is associated with a greater likelihood of cessation in smokers not ready to quit but willing to reduce smoking.<sup>11,12</sup> The likelihood of successful reduction leading to cessation increases significantly if reduction is greater than 50%.<sup>13</sup>

### Safety

The safety of Nicorette Gum or Inhalator use alongside cigarette smoking was assessed in the *Cut Down with Nicorette then Stop* completely clinical trial programme, which found an adverse event profile similar to that seen in abrupt cessation studies.<sup>14</sup>

### ***Cut Down with Nicorette then Stop* product range**

Nicorette Gum and Nicorette Inhalator are licensed for use with the new *Cut Down with Nicorette then Stop* indication. The product range available is as follows:

Product	Pack Size
<b>Nicorette Gum</b>	
Nicorette Gum Freshmint	4mg – 30s
Nicorette Gum Freshmint, Mint and Original	4mg – 105s
Nicorette Gum Freshmint and Original	2mg – 30s
Nicorette Gum Freshmint, Mint and Original	2mg – 105s
<b>Nicorette Inhalator</b>	
Nicorette Inhalator	10mg – 6s (starter pack)
Nicorette Inhalator	10mg – 42s

Further Nicorette products available for abrupt cessation are:

Product	Pack Size
<b>Nicorette Patch</b>	
Nicorette Patch	15mg – 7s
Nicorette Patch	10mg – 7s
Nicorette Patch	5mg – 7s
<b>Nicorette Nasal Spray</b>	
Nicorette Nasal Spray	1 pack – 10ml

<b>Nicorette Microtab</b>	
Nicorette Microtab	2mg – 30s
Nicorette Microtab	2mg – 105s

### Price

Nicorette Gum and Inhalator are available at the same recommended retail price (RRP) for both *Cut Down with Nicorette then Stop* and abrupt cessation uses. Actual costs may vary depending on retailer.

### Smoking cessation policy

The Government's White Paper on Tobacco, *Smoking Kills*, states that smoking is the single biggest public health risk in Britain<sup>4</sup>, and it is a major contributor to health inequalities.<sup>15</sup>

The Government has laid out plans to lower the number of adult smokers in the UK to 21%<sup>3</sup> by 2010. They have made a significant commitment to provide wider access to NRT and stop-smoking services to bridge health inequalities in the UK population.<sup>5</sup>

The White Paper on tobacco control suggests that Health Authorities, with their PCTs, develop comprehensive local strategies to tackle smoking, including the development of specialist smoking cessation services, providing advice and support to other healthcare professionals and funding of NRT. With this in mind, the following strategies have been put into place:

- Smoking and smoking cessation feature prominently in the new GMS contract, in relation to secondary prevention of coronary heart disease, stroke or transient ischaemic attacks, hypertension, diabetes mellitus, chronic obstructive pulmonary disease and asthma<sup>16</sup>.
- The new pharmacy contract aims to integrate pharmacists into the wider primary healthcare team, and this is a particularly important step for smoking cessation – a public health priority for pharmacy under the new contract is reducing smoking<sup>3</sup>.

The Government has targets to reduce the number of smokers and has been developing services for smokers to encourage smoking cessation with the aim of reducing tobacco-related death and disease in the UK.

### Further information

- Nicorette Helpline – 0800 244 838
- Website – [www.nicorette.co.uk](http://www.nicorette.co.uk)
- Nicorette Press Office: Mary Barrington-Ward (tel: 020 7108 6066) or Lucy Day (tel: 020 7108 6080) or e-mail: [mary.barringtonward@shirehealthlondon.com](mailto:mary.barringtonward@shirehealthlondon.com) or [lucy.day@shirehealthlondon.com](mailto:lucy.day@shirehealthlondon.com)

### References

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5. <http://www.dh.gov.uk/assetRoot/04/10/57/13/04105713.pdf> Delivering Choosing Health: making healthier choices easier. A Department of Health White Paper. 9th March 2005: 3: Annexe 1: 24

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00627, date of prep August 2005

### **Nicorette Gum Product Information.**

**Presentation:** Nicorette 4mg gum and Nicorette 2mg gum contain 4mg and 2mg of nicotine respectively in a chewing gum base. Original, Mint and Freshmint flavours. **Uses:** For the relief of nicotine withdrawal symptoms as an aid to giving up smoking. It is used to help smokers ready to stop smoking immediately and also to help smokers who need to cut down their cigarette use before stopping. **Dosage:** Smoking cessation: After 3 months ad libitum dosage, Nicorette gum should be gradually withdrawn. Smoking reduction: Use the gum between smoking episodes to reduce smoking. A quit attempt should be made as soon as the smoker feels ready. Professional advice should be sought if no reduction in 6 weeks or no quit attempt in 9 months. Each piece should be chewed slowly for 30 minutes. No more than 15 pieces of gum should be used each day. Not to be used by people under age 18 unless recommended by a doctor. **Contraindications:** Hypersensitivity. **Precautions:** Denture wearers, transferred dependence, gastritis, peptic ulcers, allergic reactions, cardiovascular disease, diabetes mellitus, hyperthyroidism, phaeochromocytoma, renal and hepatic impairment. **Pregnancy & lactation:** Only after consulting a healthcare professional. **Side effects:** Dizziness, headache, nausea, gastrointestinal discomfort, hiccups, sore mouth or throat, jaw ache, sticking to dentures. Uncommon: palpitation, erythema, urticaria, stomatitis. Rarely: atrial fibrillation, allergic reaction. **RRP (ex VAT):** 2mg x30 £3.25, 2mg x105 £8.89, 4mg x30 £3.99, 4mg x105 £10.83 **Legal category:** GSL. **PL numbers:** 00032/0248, 0249, 0250, 0251, 0283, 0295 **PL holder:** Pharmacia Limited, Ramsgate Rd, Sandwich, Kent. CT13 9NJ. **Date of preparation:** August 2005

### **Nicorette Inhalator Product Information:**

**Presentation:** Inhalation cartridge containing 10mg nicotine for oromucosal use via a mouthpiece. **Uses:** For the relief of nicotine withdrawal symptoms as an aid to giving up smoking. It is used to help smokers ready to stop smoking immediately and also to help smokers who need to cut down their cigarette use before stopping. **Dosage:** Smoking cessation: 6-12 cartridges per day for 8 weeks. Halve the number of cartridges in weeks 9 and 10. Reduce to zero by end of week 12. Smoking reduction: Use between smoking episodes to reduce smoking. A quit attempt should be made as soon as the smoker feels ready. Professional advice should be sought if no reduction in 6 weeks or no quit attempt in 9 months. Not to be used by people under age 18 unless recommended by a doctor. **Contraindications:** Hypersensitivity, non-tobacco users. **Precautions:** Best used at room temperature. Peptic ulcer, cardiovascular disease, systemic hypertension, peripheral vascular disease, diabetes mellitus, hyperthyroidism, phaeochromocytoma, hepatic or renal disease, gastritis. **Pregnancy & lactation:** Only after consulting a healthcare professional. **Side effects:** Cough, irritation of throat and mouth, headache, rhinitis, pharyngitis, stomatitis, dyspepsia, anxiety, nausea, dry mouth, chest pain, skeletal pain, diarrhoea, flatulence, local paraesthesia, allergy, depression, vomiting, dyspnoea, thirst, gingival irritation, hiccups, palpitations. **RRP (ex VAT):** 6-Starter pack- (£3.39), 42-Refill pack-(£11.37). **Legal category:** P. **PL holder:** Pharmacia Limited, Ramsgate Road, Sandwich, Kent. CT13 9NJ. **PL number:** 00032/0280. **Date of preparation:** August 2005