

## Questions and answers about NicoBloc

### For healthcare professionals and consumers

#### 1 How does NicoBloc work?

##### Response

NicoBloc is a viscous fluid, which is applied to the filter of the cigarette immediately before smoking. It works by trapping the nicotine and tar in the filter of the cigarette as the cigarette is smoked.

NicoBloc does not work by a chemical reaction with the smoke. NicoBloc works is by cooling the smoke down as it is sucked through the filter. The smoke passes through a moist part of the filter causing a proportion of the tar and nicotine vapour molecules to condense back into solid form and stick to the filter material.

What makes NicoBloc unique is the research that went into finding a fluid combination that a) trapped up to 99% of tar and nicotine, b) was completely safe (NicoBloc is made from food grade ingredients), c) has a pleasant taste and d) does not dry out because of the hot smoke passing through it.

NicoBloc thus prevents nicotine and other chemicals entering the body allowing the body to reduce nicotine intake over a six-week period and significantly increases the prospects of smoking cessation.

#### 2 Is it safe?

##### Response

##### Background

NicoBloc is applied to the cigarette and not to the person. Even though NicoBloc is not consumed by the patient, the ingredients of NicoBloc are food grade additives safe for human consumption.

NicoBloc is not subject to any licensing regulations either as a medicine or as a medical device.

NicoBloc can be ingested without ill effects and there are no known contraindications. NicoBloc is safe for use for people on medication or with medical conditions.

##### NicoBloc position

As a company, NicoBloc plc only comments upon the quantified tar and nicotine reductions and does not make any claims that using NicoBloc makes cigarettes safer. There are many other substances in cigarettes that may be hazardous to health and the use of NicoBloc is a means to an end not a method of making smoking safer.

Although it may be true that reducing tar and nicotine intake contributes to a lower risk, this is not a claim NicoBloc makes. However, published independent research<sup>1,2</sup> has shown that the use of NicoBloc does reduce Carbon Monoxide (CO) intake by 59% and causes smaller (but not significant) increases in heart rate, blood pressure and pulse rate compared to untreated cigarettes.

#### 3 Does using NicoBloc make cigarettes safe to smoke?

##### Response

##### NicoBloc position

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1 Pickworth, W.B., Fant, R.V., Nelson, R.A. and Henningfield, J.E. Effects of smoking through a partially occluded filter. *Pharmacology, Biochemistry and Behaviour* vol 60, no 4, pp817-21, 1998.

2 Gariti, P. & Alterman, A et al (2004) Adding a nicotine blocking agent to cigarette tapering *Journal of Substance Abuse Treatment* 27 (2004) 17–25

3 Gariti, P. & Alterman, A. (1997) Testing a smoking cessation aid<sup>3</sup>. College on Problems of Drug Dependence. 59th Annual Meeting. Nashville TN June 1997. In: L.S. Harris (ed), *Problems of Drug Dependence*. NIDA Research monograph 178. p.158.

4 Gariti, P. & Alterman, A et al (2004) Adding a nicotine blocking agent to cigarette tapering<sup>4</sup> *Journal of Substance Abuse Treatment* 27 (2004) 17–25

#### 4 What is meant by the claim 'NicoBloc absorbs up to 99% of tar and Nicotine'?

##### Response

###### Background

Tests to measure tar and nicotine reductions can be performed primarily in 2 different ways; either using smoking machines or measuring physiological reductions in plasma nicotine (using blood tests). The tests measure different end points.

NicoBloc's claims are based on smoking machine tests which conform to strict ISO standards and are used by Government-appointed laboratories to determine the differences between brands of cigarettes in terms of nicotine and tar yield. They measure in absolute terms what is or is not coming out of the cigarette. The tests are valid for what they objectively measure which is the differences between NicoBloc-treated and -untreated cigarettes in tar and nicotine yield.

Generally smoking cessation commentators prefer biochemical measures of nicotine reduction (through blood samples) over machine tests. The physiological blood tests measure the fall in nicotine levels from a base position of a smoker. Every smoker has a base level and when the level starts to fall, this is what causes withdrawal symptoms and the urge to smoke. If the smoker stops smoking, the nicotine level will gradually diminish; it doesn't go down to zero straightaway.

The main reason for why smoking cessation commentators prefer for biochemical measures is that it is felt that in extrapolating from standard smoking machine tests to human smokers, humans tend to get more out of their cigarettes than the machines do.

However it is well known that there is marked individual variability in nicotine replacement plasma levels achieved irrespective of the reported amount of cigarettes smoked. (Hurt et al., 1993<sup>5</sup>; Dale et al., 1995<sup>6</sup>). Also the publication 'Health Consequences of Smoking: Nicotine Addiction a Report of the Surgeon General 1988', illustrates significant differences between smokers with some smokers absorbing 82-92% of the inhaled nicotine, those that didn't inhale deeply absorbing 29% and non-smokers who were told to inhale deeply only metabolised 30-66% of the nicotine<sup>7</sup>. This means it is more difficult to predict the effectiveness of an approach for any individual smoker.

###### Evidence

For NicoBloc there are three independent sets of results in existence<sup>8</sup>. Two of these, using smoking machines, are in close agreement, with tar and nicotine reductions in the 88–99% range<sup>9,10</sup>. The third<sup>11</sup> shows (tar) 20% and (nicotine) 30% reductions, although the reductions quoted would appear to be insufficient to account for the physiological reductions in plasma nicotine boost (45%) also reported in the same paper. Given this inconsistency, these results must be treated with caution, and the balance of evidence is therefore in favour of the two sets of results which broadly agree.

It should further be noted that there are no ready physiological tests for measuring reductions in tar derived from cigarettes by human smokers, and smoking machines supply the only data available.

For NicoBloc the only physiological data currently published are those by Pickworth et al<sup>9</sup> showing NicoBloc achieving ~45% reduction in plasma nicotine boost. In addition there was a 59% reduction in CO. These are very encouraging results in their own right, as we wouldn't expect to see a 99% reduction in blood nicotine levels.

#### 5 What evidence is there for NB? There appears to be very little published in the way of clinical trials providing evidence of effectiveness in smoking cessation

##### Response

###### Background

Clinical trials are used by pharmaceutical medicines to obtain evidence of efficacy in order to obtain a regulatory licence or Marketing Authorisation.

NicoBloc is an FDA food grade approved substance (corn syrup solution) and as such, is not subject to any licensing regulations either as a medicine or as a medical device.

5 Hurt, R. D., Dale, L. C., Offord, K. P., Lauger, G. G., Baskin, L. B., Lawson, G. M., Jiang, N.-S., & Hauri, P. J. (1993). Plasma nicotine and cotinine levels during nicotine-patch therapy. *Clinical Pharmacology and Therapeutics*, 54, 98– 106.

6 Dale, L. C., Hurt, R. D., Offord, K. P., Lawson, G. M., Croghan, I. T., & Schroeder, D. R. (1995). High-dose nicotine patch therapy: Percentage of replacement and smoking cessation. *Journal of the American Medical Association*, 274, 1353– 1358.

7 Health Consequences of Smoking: Nicotine Addiction a Report of the Surgeon General. 1988

8 [http://www.nicobloc.com/Professionals/professional\\_home.asp](http://www.nicobloc.com/Professionals/professional_home.asp) - Summary of NicoBloc research. Accessed 5 Mar 2004.

9 Stillwell & Gladding, New York (1st series - February 1989)

10 Stillwell & Gladding, New York (2nd series - April 1993)

11 Pickworth, W.B., Fant, R.V., Nelson, R.A. and Henningfield, J.E. Effects of smoking through a partially occluded filter. *Pharmacology, Biochemistry and Behaviour* vol 60, no 4, pp817-21, 1998.

NicoBloc is being brought to market by a relatively small company and small companies cannot easily fund the hundreds of thousands of pounds needed for even a single clinical trial when the report will not be published for at least a couple of years.

#### NicoBloc position

NicoBloc does not claim efficacy in terms of smoking cessation. NicoBloc only claims it reduces the available nicotine and tar inhaled by the smoker.

The logical assumption is that it could provide a useful aid to a smoker seeking to quit; but NicoBloc resists making the claim until the evidence is available.

#### Evidence to date

Although NicoBloc has no large database of published clinical trials, the few trials that exist and the evidential data available from occupational health workplace schemes are very encouraging.

#### **The Rosen Programme – study of smokers in workplace NicoBloc schemes. 1998-2000<sup>12</sup>.**

The Rosen Stop Smoking Programme (which featured the use of NicoBloc) was carried out in the workplace and involved 680 smokers by the year, 2000. This was an Occupational Health initiative and not a clinical trial as such. The programme involved the use of NicoBloc, along with a series of counselling sessions where the behavioural modification, goal-setting and other aspects were also recognized as important.

The outcome was that 491 completed the course (72%), and of those that completed the six week programme, 285 quit smoking, a quit rate of 58%. Including the drop outs in the final figures this gives an overall outcome of 42% quitting. Measuring the overall reduction in cigarette consumption, there was a 77% reduction.

#### **Gariti, P. & Alterman, A. (1997) Testing a smoking cessation aid<sup>13</sup>.**

In this small study of 18 patients, 67% of the participants completed the 6 week protocol, 50% (9/18) of all participants reported nonsmoking at the end of 6 weeks and 39% (7/18) reported being continuously smoke free one month later, confirmed by CO readings <.010.

#### **Gariti, P. & Alterman, A et al (2004) Adding a nicotine blocking agent to cigarette tapering<sup>14</sup>**

This was a double blind, placebo controlled, 6 week smoking cessation study of 60 participants. 55% completed treatment, though the large dropout rate was partly attributed to the study design and the recruitment of less motivated participants

Both groups showed about 60% reduction in smoking. Those that went back to smoking maintained a lower level of consumption. There were significant nicotine and CO reductions in both groups. Surprisingly, the placebo showed higher plasma nicotine and CO reductions than NicoBloc. The placebo was applied to the cigarette in a way similar to NicoBloc and we can assume that it had a similar mode of action to NicoBloc. The placebo was supplied by the manufacturers of NicoBloc and a letter on file indicates that it was supplied for comparing taste and satisfaction differences and not to compare nicotine reduction properties.

## **6 Some forms of gradual reduction change the way people smoke, increasing CO intake and increasing the dependence of the smoker on the last 3-4 cigarettes.**

### **Response**

#### Background

In some studies where smoke dilution devices have been used to reduce nicotine and CO exposure, the effect has resulted in changes in smoking behaviour to compensate for the reduction in nicotine delivery. One study reported increased rate of puffing and total number of puffs when smoking with a ventilated filter<sup>15</sup>; another reported smoking more cigarettes, taking larger and more closely spaced puffs when nicotine exposure was reduced through brand switching.<sup>16</sup>

#### Evidence

Research with NicoBloc shows that unlike other smoke dilution techniques that have been tried in the past such as 'cigarette fading' or 'nicotine tapering', NicoBloc does not cause smokers to significantly alter their smoking behaviour. With NicoBloc the number of puffs and the time to smoke did not differ as a result of the number of drops used<sup>17</sup>. They do not take deeper puffs although they do find that it gets harder to draw as more fluid is used.

The psychology of smoking is complex. Anecdotal reports confirm that this effect has helped people make the final push to give up smoking. This is supported by the underlying psychology theory of work vs. reward.

12 Rosen Holding Ltd. Data on file

13 Gariti, P. & Alterman, A. (1997) Testing a smoking cessation aid<sup>13</sup>. College on Problems of Drug Dependence. 59th Annual Meeting. Nashville TN June 1997. In: L.S. Harris (ed), Problems of Drug Dependence. NIDA Research monograph 178. p.158.

14 Gariti, P. & Alterman, A et al (2004) Adding a nicotine blocking agent to cigarette tapering<sup>14</sup> Journal of Substance Abuse Treatment 27 (2004) 17–25

15 Henningfield, JE, Kozlowski LT, Benowitz NL: A proposal to develop meaningful labelling for cigarettes. JAMA 272-312-314:1994.

16 Zacny JP, Stitzer ML.: Cigarette brand-switching: Effects on smoke exposure and smoking behaviour. J. Pharmacol. Exp. Ther. 246:619-627:1988

17 Pickworth, W.B., Fant, R.V., Nelson, R.A. and Henningfield, J.E. Effects of smoking through a partially occluded filter. Pharmacology, Biochemistry and Behaviour vol 60, no 4, pp817-21, 1998.

## 7 How does NicoBloc compare with NRT (Nicotine replacement therapy)?

### Response

#### Background

NRT has long been established as one of the key pillars of smoking cessation therapy and has been included in smoking cessation guidelines both nationally and internationally. Nicotine replacement therapies in various forms, such as patch, gum, spray, and inhalers, are thought to aid smoking cessation by means of a gradual reduction in exposure to nicotine

However when reviewing the body of evidence it is worth noting that The Cochrane Review of NRT<sup>18</sup> found that over half the 110 trials reviewed failed to show a significant (95% confidence) benefit of NRT over no treatment.

This in no way discredits NRT, but goes to illustrate the difficulty smokers experience in attempting to quit. NicoBloc's own data from 560 respondents using NicoBloc, indicates that roughly 76% of them have failed to quit with NRT and are looking for something different to try.<sup>19</sup>

The most recent NICE guidance on Smoking cessation services was published in February 2008<sup>20</sup>. It lists three pharmacotherapies which have been proven to help people stop smoking – NRT, varenicline and bupropion.

Amongst its recommendations it is worth noting the following

- *'pharmacotherapies (medicines) work best when combined with support such as that offered by an NHS Stop Smoking Service'.*
- *'Do not favour one medication over another. The clinician and patient should choose the one that seems most likely to succeed'*

#### NicoBloc position

NicoBloc does not compare itself with NRT. NicoBloc offers another choice to the would-be quitter

The logic of the NicoBloc approach is similar to NRT, in that NicoBloc gradually reduces the intake of nicotine and tar. However, in addition, NicoBloc assists with the underlying psychology of work vs. reward. Anecdotal reports confirm that this effect has helped people make the final push to give up smoking.

The evidence base for NicoBloc however is predominantly from occupational health workplace schemes, not trials, ie NicoBloc has good experiential data. These schemes have been run in conjunction with counselling programmes and the smoker has not been left in isolation. Counselling support has also been recognised by NICE for many years as significantly improving would-be quitters' chances of success.

NicoBloc recognises the importance of this and has a website providing support, motivation, target calculators to help determine target reduction levels and so on. In conjunction with counselling, NicoBloc has demonstrated proven success.

## 8 Does NicoBloc alter the taste of a cigarette?

### Response

#### Background

The taste of a cigarette mainly comes from the tar. Taste is not something that can be measured empirically as it is a subjective measure and would seem that we are dealing with the perception of taste in this case.

#### Evidence

With NicoBloc it would appear that a third reduction in tar does not significantly alter the taste. As the body gets accustomed to this lower level of tar, when 2 drops are used and the tar intake is further reduced, the smoker does not perceive a significant reduction in taste and similarly after a week of using 2 drops going on to 3 drops with approximately 99% of the tar restricted, smokers still perceive that the taste has not changed significantly.

If a smoker goes straight to 3 drops without gradually reducing then they do notice a change in the taste and conversely if having got used to 1, 2 or 3 drops of NicoBloc on their cigarettes and then smoking an untreated cigarette, they report that their untreated cigarette tastes much stronger than they remembered.

A useful analogy might be the cutting down of sugar from tea by first getting used to 2 spoons of sugar from 3 spoons, then going to one spoon and then eventually cutting it out altogether.

In **Gariti, P. & Alterman, A. (1997) Testing a smoking cessation aid**<sup>21</sup> Smokers in the trial reported satisfaction with the treatment.

18 Silagy, C., Lancaster, T., Stead, L., Mant, D and Fowler, G. Nicotine replacement therapy for smoking cessation (Cochrane Review). In: The Cochrane Library, Issue 1, 2004. Chichester, UK: John Wiley & Sons, Ltd. (amended 20 Aug 2002)

19 Rosen Holding Ltd Data on file

20 NICE public health guidance 10 Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach<sup>1</sup> communities. February 2008

21 Gariti, P. & Alterman, A. (1997) Testing a smoking cessation aid<sup>21</sup>. College on Problems of Drug Dependence. 59th Annual Meeting. Nashville TN June 1997. In: L.S. Harris (ed), Problems of Drug Dependence. NIDA Research monograph 178. p.158.

In **Pickworth et al 1998**<sup>22</sup>, in the six subjective measures – satisfaction, taste, strength, hotness, like and harshness - there was no significant difference between using untreated cigarettes and NicoBloc. The only measure to show significance was that it became harder to draw as the drops increased. This is as expected and supports the behavioural aspect that the work/reward ratio changes as drops increase and this encourages the smoker to eventually stop smoking.

## 9 Does NicoBloc alter a smoker's satisfaction with their cigarette?

### Response

As mentioned above, published research<sup>19</sup> showed that smokers' satisfaction with their cigarette did not alter significantly when using NicoBloc.

## 10 Are smokers satisfied with the NicoBloc method and do they stick with it.

### Response

#### Evidence

There appears to be quite a high level of compliance with NicoBloc.<sup>19,20</sup> In these 2 published trials people tended to adhere to the programme and reported their satisfaction with it.

The evidential data from the occupational Health workplace schemes run under the Rosen Programme<sup>23</sup> shows that out of 680 smokers who enrolled on the NicoBloc programme, 72% completed the programme and overall 42% were able to quit smoking, through this approach.

## 11 Why are withdrawal symptoms less when using NicoBloc?

### Response

#### NicoBloc position

It would appear that a third reduction in nicotine intake is not enough to cause any withdrawal symptoms but is enough to start the weaning off process. As smokers gradually get used to lower levels of nicotine, when they do eventually stop smoking they are doing so from a much lower level of say smoking 3 cigarettes a day and used to just 1% of nicotine compared to cold turkey where they are stopping from say 20 a day at 100% nicotine it is logical to assume that their withdrawal symptoms would be much less and more tolerable.

#### Evidence

**Gariti, P. & Alterman, A. (1997)**<sup>19</sup> found there were no additional cravings and that those who were still smoke-free after one month reported only mild or moderate withdrawal symptoms. **Gariti, P. & Alterman, A et al (2004)**<sup>22</sup> found that those that did go back to smoking maintained a lower level of consumption.

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<sup>22</sup> Pickworth, W.B., Fant, R.V., Nelson, R.A. and Henningfield, J.E. Effects of smoking through a partially occluded filter. *Pharmacology, Biochemistry and Behaviour* vol 60, no 4, pp817-21, 1998.

<sup>23</sup> Rosen Holdings Ltd. Data on file