

Dear Colleague,

New Advice on Use of Nicotine Replacement Therapy (NRT): wider access in at-risk populations

I am writing to let you know about new advice relating to all forms of Nicotine Replacement Therapy (NRT) and its use in smoking cessation by:

- adolescents of 12 years and over,
- pregnant or breast-feeding women,
- smokers with underlying disease such as cardiovascular, hepatic and renal disease, diabetes mellitus and those taking concurrent medication.

This follows expert advice from a Working Group of the Committee on Safety of Medicines (CSM) on NRT. The Working Group recognised that while nicotine has pharmacological effects, in most circumstances, the well-established dangers of continued smoking far outweigh any risk from NRT. As a healthcare professional, you may be asked to advise on the safe use of NRT in these new groups.

In summary

- **Adolescents**

NRT may be used by adolescents aged 12 to 18 years old but as there are limited data on the safety and efficacy, duration should be restricted to 12 weeks. Treatment should only be continued longer than 12 weeks on the advice of a healthcare professional.

- **Pregnancy**

Ideally, pregnant women should stop smoking without using NRT but, if this is not possible, NRT may be recommended to assist a quit attempt as it is considered that the risk to the fetus of continued smoking by the mother outweighs any potential adverse effects of NRT.

The decision to use NRT should be made following a risk-benefit assessment as early in pregnancy as possible. The aim should be to discontinue NRT use after 2-3 months. Intermittent forms of NRT are preferable during pregnancy although a patch may be appropriate if nausea and/or vomiting are a problem. If patches are used, they should be removed before going to bed at night.

- **Breastfeeding**

NRT can be used by women who are breast-feeding. The amount of nicotine the infant is exposed to from breast milk is relatively small and less hazardous than the second-hand smoke they would otherwise be exposed to if the mother continued to smoke. 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.

- **Cardiovascular disease**

Dependent smokers with a myocardial infarction (MI), severe dysrhythmia or recent cerebrovascular accident (CVA) who are in hospital, should be encouraged to stop smoking with non-pharmacological interventions. If this fails NRT may be considered but as data on safety in these patient groups are limited, initiation of NRT should only be done under medical supervision. In patients with stable cardiovascular disease, NRT is a lesser risk than continuing to smoke.

- **Diabetes mellitus**

Nicotine releases catecholamines which can affect carbohydrate metabolism. Diabetic patients should be advised to monitor their blood sugar levels more closely than usual when starting NRT.

- **Renal or hepatic impairment**

NRT should be used with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment, as the clearance of nicotine or its metabolites may be decreased, with the potential for increased adverse effects.

- **Interactions with NRT**

To date the product information for NRT has contained interactions that may occur as a result of quitting smoking rather than from NRT *per se*. The only interaction that is possibly directly attributable to NRT is with adenosine (adverse haemodynamic effects). The revised product information for NRT will take this into account.

New product information for those using NRT will not be available for about three months, with some current packs containing out-dated advice in the Patient Information Leaflet (PIL). A bridging leaflet that will be made available is attached. This will also be posted on the MHRA website and will shortly be available from doctors, pharmacists and NHS smoking clinics.

Further information on the CSM Working Group's recommendations, including the recent availability of some NRT products for 'cut down to stop' – which allows smokers to use NRT to help them reduce the amount they smoke before quitting completely - is available on the MHRA website (www.mhra.gov.uk) in a Questions and Answers document. The final report of the Working Group will also be published shortly.

Yours sincerely,

Professor Gordon Duff
Chairman, Commission on Human Medicines