

NICOTINE REPLACEMENT THERAPY: QUESTION AND ANSWER DOCUMENT

Q1. What changes have been made to the way NRT may be used?

An Expert Working Group of the Committee on Safety of Medicines (CSM) reviewed how usage of nicotine replacement therapy (NRT) could be extended to certain patient categories and recommended that restrictions on use for all NRT products should be minimised for:

- Pregnant and breast feeding women
- Patients with heart disease
- Patients with kidney/liver problems
- Patients with diabetes, and
- 12 to 18 year olds.

Q2. What has changed – why the new advice?

An Expert Working Group of the Committee on Safety of Medicines was set up to consider the current evidence on the safety and efficacy of NRT and to advise on changes that maximise the benefits and ensure that any risks there may be with NRT are balanced against the well-established dangers of continued smoking. The evidence available included a recent large study on NRT in cardiovascular disease using data from the General Practice Research Database (GPRD).

Q3. What is the advice for pregnant women who wish to use NRT?

The data available on the use of NRT in pregnancy and breast feeding women is limited, however, the dangers of continuing to smoke are well established and are likely to be considerably more damaging to mother and baby than any potential risk of NRT. In light of this, the Working Group advised that pregnant women, who cannot stop smoking on their own, can use NRT, as can breast feeding women.

Q4. What is the advice for patients with heart disease who wish to use NRT?

Stopping smoking is critical for those with heart disease as it can slow the progression of the disease. There has been a considerable amount of work on the use of NRT in this population and the data indicates that for smokers with stable heart disease, the benefits of using NRT to quit smoking out weigh any risks there may be with NRT. For those in hospital with severe heart disease, NRT can be used if recommended and supervised by the doctor treating the patient. In addition a recent large study using data from the General Practice Research Database

(GPRD) reinforced the view that the benefit of NRT for patients with heart disease outweighed any potential risk of NRT.

Q5. What is the advice for patients with diabetes who wish to use NRT?

Smokers who have diabetes have a much higher risk of heart disease and so it is particularly important that they stop smoking. Nicotine from both smoking and NRT does, however, affect carbohydrate metabolism and the absorption of insulin and in light of this, the Working Group advised that blood sugar levels should be monitored more closely than usual when NRT is started.

Q6. What is the advice for adolescents who wish to use NRT?

In advising that NRT could be used by adolescents between 12 and 18 years, the Working Group noted concerns about the number of young people who smoke. They noted that those who begin smoking as teenagers are three times more likely to become addicted smokers for life and helping teenagers to quit, with the help of NRT, could prevent decades of continued tobacco use and subsequent ill-health. Studies indicate that NRT was as well tolerated by teenagers as it is in adults and would certainly be safer than smoking. Furthermore, young patients are much more likely to have better general health than older smokers. The Working Group also considered that there was no evidence that indicated adolescents would abuse/misuse NRT. The Working Group did, however, advise that if a teenager needs to use NRT for longer than 12 weeks, they should discuss this with a healthcare professional (such as a doctor, pharmacist or nurse).

Q7. With the 'reduce to quit indication', is it safe for people to continue smoking whilst using NRT?

It is well-established that if a smoker takes in nicotine from more than one source (e.g. smoking combined with NRT), they adjust the amount of nicotine so as to produce the "satisfaction" level they get from smoking. In addition, even if higher than usual blood nicotine levels were achieved, this was not likely to be associated with increased risk of adverse effects in most smokers. The Working Group was satisfied that the quit rate of 8.6% reported in industry trials indicated that reduce to quit products did help some smokers, who were not prepared to stop abruptly, to quit. However, it was considered that certain patient groups, including pregnant women and those with serious heart, kidney and liver disease, should use reduce to quit products only with appropriate medical advice.

Q8. Which NRT products can I use to help me to reduce the amount I smoke if I am not ready to stop immediately – can I use any NRT products?

Three products are indicated for this use. These are Nicorette 2mg gum, Nicorette 4mg gum and the Nicorette inhalator. There are other NRT products available, however, these are currently only recommended to help smokers stop altogether.

Q9. Have there been reports of side effects associated with NRT?

All medicines have the potential to cause side effects. Most side effects experienced with NRT are not serious and are predictable from the known actions of nicotine - similar to what is experienced by nicotine obtained by smoking.

Q10. Can I use a combination of NRT products to help me quit smoking?

Yes. The working Group has recommended that any warnings on NRT products not to use more than one product at a time should be removed, to allow users to identify and use the combination that is most appropriate for them.

Q11. What other support is there to help me stop smoking?

The NHS Stop Smoking Services have helped thousands of smokers to quit through a range of advice and support. Between April 2004 and September 2004 around 107,800 smokers kicked the habit at the four-week follow up stage after setting a quit date with the help of the [NHS Stop Smoking Services](#). The figures show that the services, set up as part of the Government's strategy to tackle the huge toll of disease and death caused by smoking have been highly successful at helping smokers to give up. Specialist services are also available to help pregnant women stop smoking. A formal research based evaluation of the NHS Stop Smoking service programme has concluded that around 15 per cent of smokers who set a quit date with the services can be expected to remain non-smokers after a year

Q12. Will I be able to get NRT on a prescription?

Just because a medicine is available over the counter (OTC) does not mean that it is no longer available on prescription and you can access NRT via your doctor if you prefer.

Q13. Why does the current PIL in my pack of NRT not carry the new advice?

The advice of the Working Group of the positive risk benefit balance in the patient groups discussed above has just recently been issued. It would not be right to delay the announcement until the PIL and package label has been updated when there is clear advice from experts on a positive risk benefit. Until the updated labels and PILs are in place an interim leaflet will shortly be available from doctors, pharmacists and NHS smoking clinics and is also available on the MHRA's website (www.mhra.gov.uk).

Q14. How will you know if the wider use of NRT actually works?

The MHRA is monitoring a questionnaire-based study which is being run by an NRT manufacturer. The programme is aimed at comparing the effects of the wider use of NRT on reducing to quit and actually committing to quit. Preliminary results may be available in the 1st Quarter of 2006.

Q15. What is the relationship between the Committee on Safety of Medicines (CSM) and the Commission on Human Medicines (CHM)?

The former Committee on Safety of Medicines (CSM) was the independent Committee of scientific experts who advised Government on the safety, quality and efficacy of medicines. Following a review of the Medicines and Healthcare products Regulatory Agency's (MHRA's) independent advisory structure, the Commission on Human Medicines (CHM) was established on 30 October 2005. The CHM combines the functions of the former Medicines Commission and CSM.