

NOTE FOR MR P ADAMS

IMMEDIATE COMMENTS ON NICOTINELL, TTS STOP SMOKING PATCHES

(EX CIBA GEIGY, NEW ZEALAND)

1. The above device should be taken seriously. The full prescribing information is knowledgeable in relation to nicotine and the accompanying handbook is detailed. It has probably been written by Dr. M. A. H. Russell of the Institute of Psychiatry, London U.K. who is known to BATCo's R & D Staff. The device administers nicotine through the skin, from a patch normally worn on the abdomen.
2. The patches contain sufficient nicotine to mimic 'trough' levels in moderate/heavy smokers but will not necessarily match the maximum levels immediately after smoking a cigarette. Nevertheless, substantial amounts of nicotine are delivered (maximum 21 mg/24 hours, about 50% of that taken in by a 40 a day smoker).

Incidentally the product strengths are not 10, 20 and 30 mg of nicotine as reported in the note from WD & HO Wills, NZ. They are 17 mg, 35 mg and 52.5 mg in products with surface areas of 10, 20 and 30 cm² respectively.

They are probably manufactured by Ciba Geigy in the U.K. at Manchester. The nicotine is almost certainly derived from nicotiana species and is not synthesized. Where is it obtained from?

3. We are of the opinion that the patch is efficacious in the mode of administration of nicotine, i.e. the nicotine absorbed reaches the brain rapidly and without prior metabolism.
4. In marketing terms the product appears to have achieved moderate success (15,000 out of 700,000 smokers are claimed to have tried the product), but since the TV advertising campaign mentions that stocks have temporarily run out, it is difficult to establish whether a higher penetration is possible.
5. The product is advertised on the basis of being an aid to smoking cessation by Ciba Geigy. To what extent it might work as an alternative to cigarettes for those who wish to continue to receive nicotine is not known and we recommend that this is investigated (see below).

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RECOMMENDATIONS

1. We have made provisional arrangements with Professor David Warburton, University of Reading, to test the effectiveness of Nicotinell in a human behavioural test (vigilance), probably against the same subject group smoking conventional cigarettes. The exact design of this study is not yet finalized but will probably involve using some 12 subjects (we have 21 52.5 mg patches currently available) and will require ethical approval from Reading University.
2. We will endeavour to obtain more samples of Nicotinell (including those at lower strengths).
3. We are seeking a general medical opinion on Nicotinell from our consultant Dr F J C Roe.
4. We should consider examining the rival product from Stowic Resources U.K. in the same way as Nicotinell. In the first instance Stowic Resources should be invited to a meeting in Millbank, to include senior staff.

L J Rudge
R E Thornton Corporate R & D

cc: Sir Patrick Sheehy
Mr B D Bramley
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