



2008

RE: Use During Pregnancy or Breast-feeding

Dear Health Care Professional;

Thank you for your recent request for information regarding the T.R.U.E. Test® Allergen Patch Test. We hope the following provides you with the information you require.

As noted in the package insert, the safety and efficacy of T.R.U.E. TEST in women who are pregnant or breast-feeding is unknown. Pre-market clinical trials of T.R.U.E. TEST excluded pregnant women such that there is no clinical experience in this patient population.

Few if any controlled trials of conventional patch testing have been performed in women who were pregnant or breastfeeding therefore it has not been substantiated whether the application of the T.R.U.E. Test during pregnancy alters reproduction capacity or affects the developing fetus. T.R.U.E. TEST has been assigned a pregnancy Category C level of fetal risk by the Food and Drug Administration. Some allergens included in T.R.U.E. TEST (i.e., nickel sulfate, potassium dichromate, epoxy resin, cobalt dichloride and thiuram mix) are considered suspect carcinogens, and formaldehyde is a known carcinogen - even though all are used in very low concentrations in T.R.U.E. TEST. **Therefore, T.R.U.E. TEST should only be used in pregnant women if clearly needed, and when the potential benefit justifies the potential risk to the fetus.**

It is unknown whether T.R.U.E. TEST panel allergens could be expressed in breast milk. As noted above, some allergens are suspected or known carcinogens. It is also unknown if infants or children consuming this breast milk could be affected by the presence of T.R.U.E. TEST allergens. Therefore, T.R.U.E. TEST should be used cautiously, if at all, in women who are breast-feeding.

Please let us know if we can provide any further information about patch testing with T.R.U.E. TEST that may be helpful to you or your patients. Once again, thank you for the opportunity to serve you.

Sincerely,

A handwritten signature in black ink that reads "Kim M. Sullivan". The signature is written in a cursive style with a large, sweeping flourish at the end.

Kim M. Sullivan
V.P. Regulatory/Research
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