

Dear Healthcare Provider,

Metanx[®] is a safe and effective medical food for patients who present with endothelial dysfunction associated with diabetic peripheral neuropathy (DPN). One of the primary ingredients in Metanx[®] is the biologically active stereoisomer L-methylfolate, the pure stable crystalline form of the naturally-occurring predominant form of folate. L-methylfolate is involved in the synthesis of nitric oxide, a potent vasodilator and regulator of vascular homeostasis, which is critical for DPN patients.

Recently, a company has launched a product, Folast[™], claiming to use the dietary ingredients L-methylfolate-B₆-B₁₂ and is listed as a generic equivalent to Metanx[®]. In fact, scientific analytic testing has revealed that 50% of the methylfolate in Folast[™] is in the D-methylfolate or racemic form. Also, its manufacturer has confirmed this on its own label, explicitly stating that it does not claim to be therapeutically equivalent to any product, including Metanx[®].

The D-methylfolate in Folast[™] presents a potential medical concern because the body can't metabolize the "D" isomer. The biologically inactive "D" form of methylfolate is inferior to L-methylfolate because it has been shown to exhibit negative biological effects including, but not limited to:

- Two times slower clearance from the body compared to L-methylfolate;
- Excessive storage in tissues and;
- Interaction with various folate-binding and transport proteins, acting as a competitive inhibitor of the cellular uptake of L-methylfolate

Thus, the consumption of larger amounts of the biologically inactive ingredient, D-methylfolate has raised concerns in the medical community.

Folast[™] is labeled as containing only the pure crystalline predominant form of folate, L-methylfolate, which it does not. The label does not make any reference to the "D" isomer. Because of this labeling, pharmaceutical databases have mistakenly classified this inferior product as a generic for Metanx[®]. Metanx[®] contains only the "L" form active isomer of methylfolate.

We take pride in the quality of our cGMP** manufactured Metanx[®]. We wanted you to know of this important difference so you can make informed decisions.

** *Current Good Manufacturing Practices* followed by the pharmaceutical and biotech firms to ensure that the products produced meet specific requirements for identity, strength, quality, and purity. FDA regulates these industries to ensure CGMPs are being followed.