

Tel 1-888-NOW-NOVA (1-888-669-6682)

## There are no AB-rated products equivalent to Miacalcin<sup>®</sup> Nasal Spray

November 2008

Dear Pharmacist:

When filling prescriptions for Miacalcin Nasal Spray (calcitonin-salmon), it is important to remember that the FDA, after identifying formulation differences between the products, established that Fortical® (calcitonin-salmon, recombinant) is NOT bioequivalent to Miacalcin Nasal Spray.

- According to the FDA Orange Book, the most widely used substitution reference source,
  Fortical and Miacalcin are not bioequivalent or AB-rated.
- There are formulation differences between Miacalcin Nasal Spray and Fortical and as a result, the products have separate reference listings in the FDA Orange Book.
- The formulations of the products include different excipients which may elicit different allergic or immunogenic responses.
- Finally, storage conditions of the products differ: After opening, Miacalcin may be stored at room temperature for up to 35 days while Fortical may only be stored for up to 30 days.
- Pharmacy computer linkages between Miacalcin and other products may not address the aforementioned inequivalencies.

Because there are no AB-rated equivalents, all prescriptions written for Miacalcin Nasal Spray should be filled with Miacalcin Nasal Spray.

Should you have any questions concerning Miacalcin Nasal Spray, please contact Novartis Pharmaceuticals Corporation at 1-888-NOW-NOVA between the hours of 8:30AM-5:00PM EST Monday-Friday.

Sincerely,

Stephen R. Cunningham, MD

Vice President & Head

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US Clinical Development &

Medical Affairs

Novartis Pharmaceuticals Corporation