

The Case for PEDIASTAT™

In earlier sections we have presented data supporting the efficacy of PEDIASTAT™ in treating diaper dermatitis and its superiority to the ointment base. The safety of miconazole is well established and generally accepted. We believe this efficacy and safety make PEDIASTAT™ a good candidate to become the first prescription drug with an indication for diaper dermatitis and the first antifungal to be approved for use in infants younger than 3 years of age.

Furthermore, we believe PEDIASTAT™ would provide a treatment alternative that will fill a need in the treatment options available to physicians. We have presented data showing that pediatricians treat most cases of diaper dermatitis and that pediatricians choose treatment on the basis of clinical criteria, using laboratory tests in less than 5% of cases. We have cited published experience that *C. albicans* could be cultured in 63% of cases where it was expected, but also in 25% of cases where it was not expected on clinical grounds. If we accept these findings as reasonably representative of the current standard of care of diaper dermatitis, the implication is clear: when no tests are done, there are no data to indicate that treatment for *C. albicans* is appropriate. Although speculative, this diagnostic ambiguity could account for the substantial use of clotrimazole-betamethasone dipropionate because it assures treatment of inflammation and covers contribution of *C. albicans*. We believe PEDIASTAT™ would provide a viable alternative given the reality of current practice.