

## Conclusions

### **PEDIASTAT™ is effective.**

- PEDIASTAT™ was clinically and statistically superior to the ointment base for diaper dermatitis in infants.
- PEDIASTAT™ demonstrated the greatest advantage over the ointment base in the subgroup of patients who had baseline cultures that were positive for *Candida albicans*.
- PEDIASTAT™ and the ointment base both produced improvement in patients who had baseline cultures that were negative for *Candida albicans*; improvement in this subpopulation was statistically significant for both formulations.
- The ointment base contains concentrations of petrolatum and zinc oxide that would qualify as an OTC drug product for diaper dermatitis under the FDA's Tentative Final Skin Protectant Monograph. However, in these trials the ointment base did not produce clinically or statistically significant improvement for the subset of patients whose baseline cultures were positive for *Candida albicans*.

### **PEDIASTAT™ is safe.**

- Tests in volunteers demonstrated little or no irritant, allergic, phototoxic or photoallergic potential
- No clinically significant adverse experiences were reported in the clinical trials.
- The only adverse experiences judged by investigators to be related to treatment occurred in the skin and resolved without sequelae. The incidence of these reactions was less than 1% for both the PEDIASTAT™ and ointment base treatment groups.
- Adverse experiences occurred half as often with PEDIASTAT™ as with the ointment base. Investigators judged virtually all these reactions to be coincidental illnesses that were unrelated to treatment.

### **PEDIASTAT™ is a valuable treatment option.**

- There are currently no prescription medications with a diaper dermatitis indication.
- There are currently no topical antifungal products approved for treatment of children younger than three years.
- PEDIASTAT™ produced an overall benefit compared to the ointment base.
- PEDIASTAT™ proved superior in patients with baseline cultures that were positive for *Candida albicans*, whereas the ointment base alone was not effective.

PEDIASTAT™ (miconazole nitrate, USP 0.25%) Diaper Rash Ointment

NDA 21-026

- PEDIASTAT™ would provide an alternative to combination products containing a corticosteroid and an antifungal because it offers the barrier protection of zinc oxide and petrolatum with antifungal activity to reduce or control *Candida albicans*.

**PEDIASTAT™ is not likely to develop miconazole-nitrate-resistant *Candida*.**

Miconazole is widely used in prescription and non-prescription products, including extensive use for vaginal yeast infections. In addition to medical use, azole molecules are widely used in agriculture. Despite extensive use, this experience indicates that reports of true resistance to miconazole are rare.