

**Johnson & Johnson Consumer Companies, Inc. *Advisory Committee Briefing Book***  
**PEDIASTAT™ (miconazole nitrate, USP 0.25%) Diaper Rash Ointment**  
**NDA 21-026**

## **PEDIASTAT™**

### **Product Indication**

PEDIASTAT™ (miconazole nitrate, USP 0.25%) Diaper Rash Ointment is indicated for infants with diaper dermatitis.

### **Product Description and Dosing**

PEDIASTAT™ (miconazole nitrate, USP 0.25%) Diaper Rash Ointment is proposed as a prescription drug ointment intended for topical use containing the synthetic antifungal agent miconazole nitrate (0.25%) in a base containing White Petrolatum, USP and Zinc Oxide, USP.

The recommended dosing is to apply PEDIASTAT™ (miconazole nitrate, USP 0.25%) Diaper Rash Ointment to cleaned skin at each diaper change until there are no longer signs of rash or irritation, or for a maximum of 7 days whichever is longer. The caregiver is advised to consult their physician if the rash becomes more severe or if the rash shows no improvement within 72 hours.