Marketing History

Marketing Experience in Other Countries

Topical 0.25% miconazole nitrate ointment has been commercially available outside the United States since the early 1990s. The initial approval of topical 0.25% miconazole nitrate ointment was obtained in Belgium in 1991. No miconazole-containing product of any strength or dosage form has been withdrawn from the market because of safety reasons.

Currently, 6 countries market an over-the-counter topical product containing 0.25% miconazole nitrate ointment (DAKTOZIN®): Australia, Belgium, Denmark, Luxembourg, Russia, and Venezuela. Six other countries have approved this drug, only one for prescription use: Argentina, Brazil (prescription), Germany, Indonesia, Israel, and Portugal. This topical product containing 0.25% miconazole nitrate ointment is indicated for the treatment of diaper dermatitis. As of September 1997, an estimated 1,124,716 units of topical 0.25% miconazole nitrate ointment have been distributed.

All reports of adverse experiences received by JOHNSON & JOHNSON affiliates since 1991 regarding this product have been reported to the Pharmacovigilance Department of Janssen Research Foundation, Beerse, Belgium. As of January 1998, the Pharmacovigilance Department reports six (6) adverse experiences or 5.3 adverse experiences per 1,000,000 units sold. Only two (2) of these six adverse experiences reported were classified as possibly related to use of the product. The two (2) adverse experiences were limited to cutaneous reactions that resolved after discontinuation of the product. One involved a 24-year old female who developed unspecified erythema while treating her newborn infant. The other was an infant who developed an allergic reaction of unknown origin and etiology after the application of DAKTOZIN®.