
PID 329.001.00070

Primary Adverse Experience: TACHYCARDIA
Other Adverse Experience: SYNCOPE (faintness upon standing)
VASODILATATION (hot flashes)
DRY MOUTH
NAUSEA
AGITATION (increased agitation)
INSOMNIA (middle, terminal insomnia)
TREMOR (hand tremors)

Demography: Age: 12 yrs Date of Birth: 02-Sep-82 Sex: Male
Height: 58 in Weight: 76 lbs Race: Caucasian

Country: United States

Medical History: Allergies to caffeine, chocolate and mold, enlarged lymph nodes, headaches, bruised foot (1990), bruised hand (1993), ear infections (1983), sinus infections (1991), sprained ankle (1992), sprained foot (1990)

Study Diagnosis: MAJOR DEPRESSIVE DISORDER

Study Drug: Imipramine

Start: 22-Feb-95

End: 24-Mar-95

AE Remarks: This 12 year old male was randomized to imipramine 50mg/day on 22-Feb-95. The patient was up-titrated to 100mg/day the following week and to 150mg/day beginning day 15.

This patient was withdrawn after 31 days because of an increased pulse rate (≥ 110 bpm) for 2 consecutive weeks which, in the investigator's opinion, was severe and related to study medication. No corrective therapy was required.