**Name of company:** Boehringer Ingelheim  
**Name of finished product:** Persantin  
**Name of active ingredient:** dipyridamole  
**Module:**  
**Report date:** 12 DEC 1989  
**Trial No. / U No.:** CT-268/U89-0021  
**Date of trial:** 17 APR 1985 - 09 FEB 1988  
**Date of revision (if applicable):**  

**Synopsis No.:**  
**Page:** 1 of 2  
**Volume:**  

**Title of trial:** A controlled trial of the effect of dipyridamole on micro-albuminuria and platelet function in childhood diabetes mellitus.  
**Principal/Coordinating Investigator:** T. M. Barratt  
**Trial sites:** Great Ormond Street Hosp/Queen Elizabeth Hosp  
**Clinical phase:** III  
**Objectives:** To assess the effect of 12 months’ treatment with dipyridamole on microalbuminuria in childhood diabetes mellitus  
**Methodology:** Randomised, placebo-controlled, double-blind parallel group study with stratification by severity of microalbuminuria  

**No. of subjects:**  
- **planned:** entered: 60  
- **actual:** enrolled: 60  
  Treatment dipyridamole:  
  entered: 29 treated:29 analysed (for primary endpoint): 25  
  Treatment placebo:  
  entered: 31 treated: 31 analysed (for primary endpoint): 28  

**Diagnosis and main criteria for inclusion:** Diabetic children with microalbuminuria  
**Test product:** dipyridamole  
**dose:** 5 mg/kg/day in 2 divided doses  
**mode of admin.:** Oral  
**batch no.:**
**Name of company:**
Boehringer Ingelheim

**Name of finished product:**

**Name of active ingredient:**

**Module:**

**Report date:**
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**Reference therapy:**
Matched placebo

dose:

mode of admin.:

batch no.:

**Duration of treatment:**
12 months

**Criteria for evaluation:**

- **Efficacy / clinical pharmacology:**
  Urine albumin excretion expressed as the geometric mean albumin to creatinine concentration ratio (UA/UC), measured 3-monthly

- **Safety:**
  Glomerular filtration rate (GFR), urinary excretion of tubular proteins (retinol binding protein and N-acetyl-beta-D-glucosamidase), blood pressure and spontaneous platelet aggregation (SPA) after 2 and 12 months

**Statistical methods:**
Analysis of variance

**SUMMARY – CONCLUSIONS:**

**Efficacy / clinical pharmacology results:**
UA/UC was not different in diabetic children receiving dipyridamole, 0.60 mg/mmol (0.42 - 0.85), compared with those receiving placebo, 0.87 mg/mmol (0.62-1.21, p=0.14) and at 3, 6 and 9 months the UA/UC was slightly higher in the dipyridamole treated group.

**Safety results:**
GFR, BP, tubular protein excretion and SPA did not differ between groups

**Conclusions:**
Dipyridamole has no significant effect on urinary albumin excretion or renal function early in IDDM