

SAFETY PROFILE OF METHYLPHENIDATE HYDROCHLORIDE-MODIFIED RELEASE (MPH-LA) IN ADULTS AND CHILDREN WITH ATTENTION DEFICIT HYPERACTIVITY DISORDERY. Ginsberg¹, T. Arngrim², A. Philipsen³, P. Gandhi⁴, C.W. Chen⁵, V. Kumar⁵, M. Huss⁶

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Introduction and objectives: The safety profile of MPH-LA in the paediatric population has been well studied. However, there are very limited studies reporting safety of MPH-LA in adults. We present the safety profile of MPH-LA in adults and from a pooled analysis in children.

Methods: Data from 3 multiple-dose, double-blind, placebo-controlled studies of 7-12 weeks duration in children with ADHD; MPH-LA (10-80mg/d) (n=314) & placebo (n=318) (aged 6-12 yrs in 2 studies & 13-17 yrs in one study) were pooled for this analysis. In addition, data from 722 adult patients, 18-60 yrs of age with ADHD receiving MPH-LA 40-80 mg/d (n=542) or placebo (n=180) from *double-blind dose confirmation phase* of 9-week duration from one study was included in the analysis.

Results: Common adverse events (AEs) reported by both adult and paediatric ADHD patients were decreased appetite, headache, nasopharyngitis, nausea, and insomnia (Table). Incidence of serious AEs (SAEs) was low with MPH-LA in both adults (0.7%) and children (0.6%) compared with placebo group (1.1% in adults and 0.3% in children).

Conclusions: Our findings show that safety profile of MPH-LA in adults is similar to that observed in the paediatric population.

Table: Adverse events (≥5%) by preferred term in multiple dose, placebo-controlled studies in adult and paediatric ADHD patients

Most common AEs	Adults		Children	
	MPH-LA N=542, n (%)	Placebo N=180, n (%)	MPH-LA N=314, n (%)	Placebo N=318, n (%)
Total number of patients with any AE	401 (74.0)	108 (60.0)	132 (42.0)	112 (35.2)
Decreased appetite	136 (25.1)	8 (4.4)	30 (9.6)	5 (1.6)
Headache	111 (20.5)	30 (16.7)	37 (11.8)	32 (10.1)
Dry mouth	110 (20.3)	4 (2.2)	0	0
Nausea	58 (10.7)	9 (5.0)	12 (3.8)	4 (1.3)
Nasopharyngitis	54 (10.0)	17 (9.4)	13 (4.1)	15 (4.7)
Insomnia	44 (8.1)	7 (3.9)	8 (2.5)	4 (1.3)
Hyperhidrosis	43 (7.9)	5 (2.8)	0	0
Palpitations	39 (7.2)	1 (0.6)	0	0
Fatigue	38 (7.0)	11 (6.1)	5 (1.6)	4 (1.3)
Dizziness	32 (5.9)	5 (2.8)	5 (1.6)	1 (0.3)
Irritability	32 (5.9)	8 (4.4)	4 (1.3)	1 (0.3)
Anxiety	29 (5.4)	1 (0.6)	3 (1.0)	0
Initial insomnia	28 (5.2)	2 (1.1)	5 (1.6)	5 (1.6)

Analysis data set: Safety population of *double-blind dose confirmation phase* of 9-week duration conducted in adult ADHD patients and pooled safety population from 3 paediatric studies.