These results are supplied for informational purposes only. *Prescribing decisions should be made based on the approved package insert in the country of prescription*			
Sponsor/company:	**sanofi-aventis**	**ClinialTrials.gov Identifier:**	**NA**
		Study Code:	**L_9557**
Generic drug name:	**Valproic acid, sodium salt**	**Date:**	**February 5th, 2007**

Title of the study:	Observation of use study with Depakine Chrono	
Investigator(s):		
Study center(s):	Multicenter (38 centers) – Saudi Arabia	
Publications (reference):		
Study period: Date first patient enrolled: 01/05/2004 Date last patient completed: 30/05/2005		Phase of development: IV
Objectives:	To assess the compliance and patient satisfaction consequences induced by the prescription of Depakine Chrono on monotherapy in epileptic patients.	
Methodology:	It is a prospective, open-label, multicentric study to assess the compliance and satisfaction consequences in epileptic patients switched from a twice daily or three times daily Valproic acid Enteric Coated regimen (included all marketed Enteric Coated formulation) to the same total daily dose of Depakine Chrono given once daily or twice daily.	
Number of patients:	Planned: 300	Evaluated: 190
Diagnosis and criteria for inclusion:	• Patient treated by Valproïc Acid tablet on monotherapy from at least 3 months • Male or female patients between 18 and 65 years inclusive • Patients currently cared for in an ambulatory setting • Patients must be able to understand the local language • Patients must be relied upon to perform the full study • Patients must sign the informed consent form after the nature of the study has been fully explained	
Investigational product:	Depakine Chrono	
Dose:	Patients on Acid Valproïc tablets in monotherapy from 3 months at least at the inclusion moment were enrolled to receive Depakine chrono in the same dose once or twice daily.	
Administration:	Oral route	
Duration of treatment: 3 months		Duration of observation: 3 months

Reference therapy:	Valproic acid Enteric Coated tablet
Dose:	
Administration:	Oral route
Criteria for evaluation:	
Efficacy:	● Compliance & patient satisfaction evaluated via a patient questionnaire. ● Clinical response ● Incidence of any relevant events
Safety:	● Collection of spontaneous reporting of adverse events
Statistical methods:	● The study group was described by demographic variables, background variables with appropriate statistics (frequency tables or mean, std., min., lower quartile, median, upper quartile and max.). ● Primary efficacy variable was Compliance & patient satisfaction while secondary variables were clinical response & safety analysis (incidence of adverse events). The data from the compliance and satisfaction questionnaire will be analyzed using SPSS. Comparisons of non parametric data will be made comparing Valproïc Acid (Day 0) and Depakine Chrono (Day 90).

<table>
<tr><td>Summary:</td><td>● All patients (190) were of no major protocol deviation. They received Depakine Chrono at the same dose of Valproic acid taken in the previously 3 months, by oral route for 90 days.
● Patients were of an average age of 26 years (18-65), average weight of 69 kgs, 51% of them were females.</td></tr>
<tr><td>Efficacy results:</td><td>190 patients -with any signs or symptoms of epilepsy and planned to take Depakine Chrono- were included, all of them were evaluable.
● Compliance: marked improvement was noticed in all attributes of compliance denoted by patient questionnaire. Significant changes were detected between the 2 study visits (p value < 0.001 "Wilcoxon matched pairs test").
● Patient satisfaction: 99% were very to fairly satisfied by the end of Depakine Chrono course.</td></tr>
<tr><td>Safety results:</td><td>30 patients (16%) experienced adverse events on the study medication.
<table><tr><th></th><th>N</th><th>% to those with AE</th><th>% to overall sample</th></tr><tr><td>Hair loss</td><td>16</td><td>53%</td><td>8.4%</td></tr><tr><td>Dizziness</td><td>10</td><td>33%</td><td>5.3%</td></tr><tr><td>Sleepiness</td><td>6</td><td>20%</td><td>3.2%</td></tr><tr><td>Weight gain</td><td>4</td><td>13%</td><td>2.1%</td></tr><tr><td>Difficulty in concentration</td><td>3</td><td>10%</td><td>1.6%</td></tr><tr><td>Sedation</td><td>2</td><td>7%</td><td>1.1%</td></tr><tr><td>Stomach Upset</td><td>2</td><td>7%</td><td>1.1%</td></tr></table>Table 3: Adverse events
● Most of adverse events were of possible relation to study medication however they restored without defect.
● None of adverse events were serious however 3 patients with hair loss and 7 patients with dizziness were restored with defect.</td></tr>
<tr><td>Date of report:</td><td>28 September 2006</td></tr>
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