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Report Title: **Sodium Valproate**
Official Information Act Request

Prepared by: **New Zealand Pharmacovigilance Centre**
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Specific Request: (Sent by email on 09 June 2021)

Under the OIA we would like to request the following information from 1 April 2018 to current date:

- *How many cases of exposure to sodium valproate during pregnancy have been reported*
- *The affects to the foetus/person, including deaths*
- *What dose of sodium valproate has caused these affects*
- *Ethnicity of person affected (if known)*

Overview

Exposure to sodium valproate during pregnancy

Cases reported to CARM - 01 April 2018 to 30 June 2021
identifying sodium valproate treatment during pregnancy 4

Note: 3 of these cases, while reported in 2018, refer to births in 2009, 2013, 2015

Dosage of sodium valproate

These 4 cases describe Intra-Uterine absorption and a dose cannot be quantified therefore
Each case has been reviewed to identify the daily dose of sodium valproate administered to the mother and this has been provided on each of the 4 cases.

mg/day	Number of Cases
1000	1
1400	1
1500	1
1800	1

Details of affects to the foetus/person

Listing of Individual case details follows.

CAVEAT DOCUMENT

Accompanying statement to data released from the

NEW ZEALAND CENTRE FOR ADVERSE REACTIONS MONITORING

The Centre for Adverse Reactions Monitoring (CARM) has only limited details about each suspected adverse reaction contained in its Database. It is important that the limitations and qualifications which apply to the information and its use are understood.

The data made available represent the collection of spontaneous reports in the CARM database associated with therapeutic products/vaccines granted regulatory approval for use in New Zealand.

Reports have been submitted to the Centre since April 1965 and in many instances describe no more than suspicions which have arisen from observation of an unexpected or unwanted event. This level of reporting is due to CARM encouraging reporters to report events they suspect may be associated with a pharmaceutical product/vaccine irrespective of whether or not they believe it was the cause. CARM accepts all reports and proof of causality is not required when submitting a report to CARM. Coincidental events that may be unrelated to pharmaceutical product/vaccine exposure may be reported. This is particularly possible when the product has widespread use, or is used in targeted strategies such as vaccination campaigns.

In most instances it cannot be proven that a pharmaceutical product or ingredient is the cause of an event in the Database. Reports vary in quality, completeness and detail and may include detail that is incorrect. Consequently, a report in the CARM database of an event does not confirm that the pharmaceutical product/vaccine caused the event.

The volume of reports for a particular product may be influenced by the extent of use of the product, publicity, nature of reactions and other factors which vary over time and from product to product. It is generally accepted internationally that systems such as CARM are subject to under-reporting which may result in scant reports for events perceived by the reporter to be minor or well recognised, whilst more serious or unexpected events are possibly more likely to be reported, even if they are coincidental. Moreover, no information is provided on the number of patients exposed to the product.

The data contained in these tables are further subject to ongoing internal quality controls, review and updating and therefore may be subject to change, particularly if follow-up information is received.

For the above reasons interpretations of adverse reaction data, and particularly those based on comparisons between pharmaceutical products, may be misleading. Any use of this information must take into account at least the above. Although this information is now released, it is strongly recommended that prior to any use of such information, CARM is contacted for interpretation.

Any publication, in whole or in part, of the obtained information must have published with it a statement:

(i) of the source of the information

(ii) that the information is not homogenous at least with respect to origin or likelihood that the pharmaceutical product/vaccine caused the adverse reaction,

(iii) that the information does not represent the opinion of the NZPhvC or CARM.

Director
New Zealand Pharmacovigilance Centre

Details of Individual cases involving Sodium Valproate

Please note - some cases are coded for the Mother and others, where a child is born, are coded for the baby. AGE indicates age when reaction noted.

REPORT	DATE	REACTIONS		DRUGS	ROUTE	DOSE/UNIT	BEGAN	ENDED	AGE	SEX	OUTCOME
128147	APR2018	FOETAL VALPROATE SYNDROME	*	VALPROATE SODIUM	IU		000109	281009	8	F	Unknown outcome
Comment:	Dose (Mother) 1000 mg per day										
128148	APR2018	FOETAL VALPROATE SYNDROME	*	VALPROATE SODIUM	IU		000412	260113	5	F	Unknown outcome
Comment:	Dose (Mother) 1400 mg per day										
128149	APR2018	FOETAL VALPROATE SYNDROME	*	VALPROATE SODIUM	IU		001214	270915	2	F	Not yet recovered
Comment:	Dose (Mother) 1800 mg per day										
128294	MAY2018	FOETAL VALPROATE SYNDROME	*	VALPROATE SODIUM	IU		001197	130898	birth	F	Not yet recovered
Comment:	Dose (Mother) 1500 mg per day										