

Sodium valproate Use in women of child bearing age

It is well established that antiepileptic medicines, including sodium valproate, are associated with congenital malformations (such as spina bifida, cleft palate and heart defects; in approximately 10% of cases), cognitive impairment, behavioural difficulties (such as autistic spectrum disorder) and developmental disorders (in up to 30-40% of cases). Sodium valproate should not be prescribe for sexually active females of child bearing age unless there is no reasonable alternative as sodium valproate has the highest risk of harm. 1,2,3

Sodium valproate continues to be prescribed for women of child bearing age.

- In calendar year 2018, 4,124 women of child bearing age received sodium valproate
- Of these, 945 (22.9%) were Māori women
- Women of child bearing age: women aged 10 to 49 years inclusive

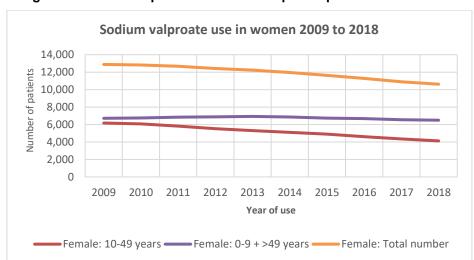


Figure 1. Women dispensed a sodium valproate product 2009 to 2018

ACC. Benefits and risks of taking antiepileptic medicine for females. Information for healthcare professionals. Treatment Safety, ACC. ACC7809. September 2017.

New Zealand Formulary (NZF). NZF v86. 2019. Available from: www.nzf.org.nz (Accessed August, 2019)

Medicines and Healthcare products Regulatory Agency (MHRA). Valproate medicines (Epilim, Depakote): contraindicated in women and girls of childbearing potential unless conditions of Pregnancy Prevention Programme are met. Published 24 April 2018. URL: <a href="https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met#teratogenicity-of-valproate-medicines. Accessed Auguat 2019.

Table 1. Women dispensed a sodium valproate product in calendar year 2018, by DHB of domicile (Women of child bearing age aged 10-49 years, outlined in red)

DHB of domicile	Female: 10-49 years		Female: 0-9 + >49 years	Female: Total number
	Number of patients	Rate / 10,000 DHB female child bearing population	Number of patients	Number of patients
Whanganui DHB	88	59.9	142	230
Wairarapa DHB	60	59.3	70	130
Hawkes Bay DHB	188	47.7	290	478
West Coast DHB	33	45.7	69	102
Taranaki DHB	131	45.4	233	364
Northland DHB	172	42.5	270	442
Waikato DHB	457	42.0	633	1,090
Lakes DHB	108	38.8	145	253
South Canterbury DHB	48	36.6	120	168
MidCentral DHB	165	36.3	351	516
Nelson Marlborough DHB	113	33.7	247	360
Canterbury DHB	485	33.6	770	1,255
Southern DHB	268	31.5	509	777
Bay of Plenty DHB	176	31.0	336	512
Tairāwhiti DHB	38	30.8	75	113
Hutt DHB	117	29.9	234	351
Waitemata DHB	409	23.7	503	912
Capital Coast DHB	212	23.0	297	509
Counties Manukau DHB	369	23.0	471	840
Auckland DHB	293	17.5	428	721
Not specified	194	-	302	496
Grand Total	4,124	-	6,495	10,619

Not specified = where the DHB of domicile is not specified in the pharmaceutical collection

Table 2. Women of child bearing age dispensed a sodium valproate product in calendar year 2018, by ethnicity

Ethnicity (Level 1)	Number of females	
European	2,681	
Maori	945	
Pacific Peoples	222	
Asian	211	
Middle Eastern/Latin American/African	55	
Other Ethnicity	3	
Residual Categories	7	
Total	4,124	

Māori females are over represented as receiving sodium valproate: with 22.9% of females of child bearing age dispensed a sodium valproate product being identified as Māori; this is against 15.8% of the total population being Māori.

Table 3. Women of child bearing age dispensed a sodium valproate product in calendar year 2018, by age band

(Women of child bearing age aged 10-49 years, outlined in red)

Age band	Total female numbers in age band	Number of Māori females in age band	Percentage of Māori females in age band	Percentage Māori female in the total female population
0 - 4 years	82	24	29.3	27.4
5 - 9 years	191	66	34.6	26.4
10 - 14 years	179	50	27.9	25.5
15 - 19 years	206	48	23.3	23.3
20 - 24 years	417	102	24.5	19.7
25 - 29 years	487	115	23.6	16.0
30 - 34 years	501	125	25.0	14.4
35 - 39 years	581	129	22.2	14.3
40 - 44 years	717	160	22.3	14.4
45 - 49 years	1,036	216	20.8	13.6
50 - 54 years	1,117	255	22.8	12.7
55 - 59 years	1,192	253	21.2	12.0
60 - 64 years	921	146	15.9	10.3
65 - 69 years	841	105	12.5	8.7
70 - 74 years	735	56	7.6	7.0
75 - 79 years	547	48	8.8	6.1
80 - 84 years	409	20	4.9	5.2
85 - 89 years	270	9	3.3	3.8
>89 years	190	3	1.6	2.6
Total	10,619	1,930		

Method

Using dispensed pharmaceuticals claims data the number of patients dispensed a sodium valproate product was determined. The Pharmaceutical Collection contains claim and payment information from pharmacists for subsidised dispensings that have been processed by the Sector Operations General Transaction Processing System (GTPS).⁴

a. Source The national pharmaceutical collection b. Period Calendar years 2009-2018 (10 years), with 2018 used for the breakdown by DHB, ethnicity etc c. Chemical ID 2166 sodium valproate d. Form ID 216605 sodium valproate injection 100 mg/mL 216604 sodium valproate oral liquid 200 mg/5 mL 216601 sodium valproate tablet 100 mg 216602 sodium valproate tablet 200 mg EC 216603 sodium valproate tablet 500 mg EC e. Parameters Number of unique patients / NHI numbers Gender

Age Ethnicity DHB

The indication for the sodium valproate is not able to be ascertained from the national collection (eg, for epilepsy or mood disorders).

Billy Allan Medication Safety Specialist Health Quality & Safety Commission Updated 22 August 2019

Ministry of Health. Pharmaceutical collection. URL: https://www.health.govt.nz/nz-health-statistics/national-collections-and-surveys/collections/pharmaceutical-collection. Accessed 19 August 2019.