

PHARMACY Bulletin

Edition 19, Issue 5

Pharmacy Department, Hospital Canselor Tuanku Muhriz (HCTM, formerly known as PPUKM)

SODIUM VALPROATE (EPILIM®) UPDATE:



**Patient
Safety
Alert**

Risk of **DECREASED IQ SCORES** in Children
after **FOETAL EXPOSURE**

VALPROATE (EPILIM®) is approved in Malaysia for the treatment of **epilepsy** and **mania** associated with **bipolar disorder**.



NEW CONTRAINDICATION

Should **NOT** be used in **FEMALE CHILDREN** / women of **CHILDBEARING** potential / **PREGNANCY**

(*unless other treatments are **INEFFECTIVE** or **NOT TOLERATED**)



CONTRAINDICATION APPLIES TO...

Epilepsy / Bipolar Disorder / Migraine prophylaxis.

EXCEPTION: Patient must **UNDERSTAND the risk** and **MEASURES** needed to **minimize the risks**.



IMPLICATIONS AFTER EXPOSURE...

"...Children exposed in utero to **VALPROATE** are at risk of serious **DEVELOPMENTAL DISORDERS** (in up to 30-40% of cases) and of **CONGENITAL MALFORMATIONS** (in 10% of cases)!..."

Graphical summary from NEAD research finding¹:



A **PROSPECTIVE** observational multi-center study (US & UK), towards **PREGNANT** women are on **monotherapy AED** (Carbamazepine, Lamotrigine, Phenytoin, Valproic acid).



...**305 mothers** and **311 children** included.
224 children completed **6 years** of follow up.

CONCLUSION

Fetal **VPA** exposure has **DOSE-DEPENDENT** associations with reduced cognitive abilities across a range of domains at 6 years old.

The positive association of **PERICONCEPTIONAL FOLATE** with **IQ** is consistent with other recent studies.

*NEAD: The Neurodevelopmental Effects of Antiepileptic Drugs



MULTIVARIATE ANALYSIS showed that in-children **age-6**, **IQ was lower** after exposure to **VPA**, having **poorly on measures executive of verbal** and **memories abilities** and on **non-verbal** and **executive functions** compared to other AEDs.

FRIENDLY REMINDERS TO HEALTHCARE PROFESSIONALS

...**ESPECIALLY** in girls and women of childbearing potential

Key Facts – Valproate▼ and Pregnancy

Name: Date:

- Valproate is an effective medicine used to treat epilepsy and bipolar disorder.
- Valproate can seriously harm an unborn child when taken during pregnancy and should be not taken by women and girls unless nothing else works.

▼ **Reporting Side Effects**
Please report any side effects you may get directly to the National Pharmaceutical Regulatory Agency (NPRA) through the website: <http://npa.moh.gov.my> (Public → Reporting → ConSERF).

What you must do

For women who are able to get pregnant (of child-bearing age):

- When taking valproate, always use reliable contraception so you do not have an unplanned pregnancy.
- Speak to your doctor if you are thinking about having a baby, and do not stop using contraception until you have done so.
- Tell your doctor at once if you think you may be pregnant or know you are pregnant.
- Never stop taking valproate unless your doctor tells you to as your condition may become worse.

Keep this card safe so you always know what to do.

MYVPA.16.11.01



A **PATIENT CARD** should be provided to all women of childbearing potential every time **VALPROATE** is dispensed.

An **ANNUAL RISK ACKNOWLEDGEMENT FORM** need to be used by the specialist at the **TIME OF TREATMENT INITIATION** and during **ANNUAL REVIEW OF VPA** treatment by the specialist.



PREGNANCY must be excluded before start of treatment with VPA, and should not be initiated in women of childbearing potential without a **NEGATIVE PREGNANCY TEST!**

Women of childbearing potential who are prescribed with VPA **MUST** use **EFFECTIVE CONTRACEPTION (intra-uterine device/implant)** without interruption during the entire duration of treatment with VPA.



Advise the patient **NOT TO STOP VPA** and to contact their Doctor urgently when planning a pregnancy **OR** in case of a suspected pregnancy.

REFERENCES:

- 1- Meador, K. J., Baker, G. A., Browning, N., Cohen, M. J., Bromley, R. L., Clayton-smith, J., Kalayjian, L. A., et al. 2013. Fetal antiepileptic drug exposure and cognitive outcomes at age 6 years (NEAD study)
- 2- Letter from SANOFI, "Valproate (Epilim): New restrictions on use.

The NEWLY Improved PPUKM Formulary App is now available on:

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PUSAT FARMASI UKM

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Creatinine Clearance (Cockcroft-Gault)

Creatinine Clearance (Paediatric)

ATC Classification
Musculoskeletal system - ANTINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

Generic Name
Celecoxib

Brand Available in PPUKM
CELEBREX® by PFIZER

Formulation
Cap 400mg

Policy
Celebrex 400mg A*: For Inpatient use only:
Acute pain: 7 days supply or max of 7 tabs (Prescriber: Palliative Care Specialist Only)
Celebrex 200mg: Status changed to Non Formulary (Bengkai DUR 2017)

Dose
Acute pain or primary dysmenorrhea: Oral:

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