

SODIUM VALPROATE RISK MINIMISATION MEASURES

IMPORTANT REMINDER
FOR HEALTHCARE
PROFESSIONALS



- ✓ Sodium valproate remains an effective treatment for epilepsy and bipolar disorders.
- ✓ Advise patients not to stop or change their sodium valproate dose without medical advice.

To prevent avoidable harm, the following risk minimisation measures (RMMs) are **REQUIRED** for all products containing sodium valproate.

1 PREGNANCY PREVENTION PROGRAMME (PPP)



Women of childbearing potential :
Contraindicated unless PPP
conditions are strictly met.

Pregnancy Prevention Programme (PPP)

- ✓ **Assess** pregnancy potential before prescribing.
- ✓ **Counsel** on the risks of valproate use during pregnancy .
- ✓ **Prevent** : Inform patient on the need for effective contraception

2 ANNUAL RISK ACKNOWLEDGEMENT FORM



Review and Reinforce

Prescriber must complete this form :

- At the **start of treatment**, and
- During every **annual review**

3 PATIENT ALERT CARD

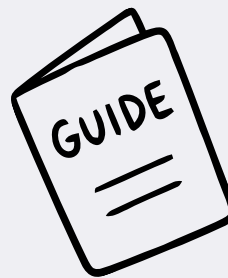


Provide :
Patient card for every patient (male or female)

Explain :
to ensure patient understand the important safety information

4 EDUCATIONAL MATERIALS

The **right information** can prevent avoidable harm.
Provide the educational material to ensure **informed decision-making**.



**FOR
MALE
PATIENTS/
CAREGIVERS**



**FOR
FEMALE
PATIENTS/
CAREGIVERS**

KEY ACTIONS FOR HEALTHCARE PROFESSIONALS



PRESCRIBE
only
when appropriate



COMPLETE
Annual Risk
Acknowledgement Form



PROVIDE
Patient Card
at dispensing



COUNSEL
on risks and
prevention measures



REVIEW
annually

together, we can make medicines safer



REPORT ADVERSE EVENTS

Report any suspected adverse
drug reactions related to
sodium valproate to the NPRA.



www.npra.gov.my

03-7883 5400



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SCAN HERE

for educational
materials (including guide for
HCPs and patients) and latest
updates



These measures are implemented under Directive under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984.
Effective date: 1 September 2025