Valproic acid

Section: 5. Anticonvulsants/antiepileptics

### Indication
- **Epilepsy or seizures**

#### ATC codes:
- N03AG01

#### Expert Committee recommendation

#### Additional notes
- Avoid use in pregnancy and in women and girls of child-bearing potential, unless alternative treatments are ineffective or not tolerated because of the high risk of birth defects and developmental disorders in children exposed to valproate in the womb.

### Formulations
- Oral > Liquid: 200 mg per 5 mL (sodium valproate)
- Oral > Solid: 200 mg (sodium valproate) enteric-coated tablet; 500 mg (sodium valproate) enteric-coated tablet; 100 mg (sodium valproate) crushable tablet

### EML status history
- First added in 1979 (TRS 641)
- Changed in 1987 (TRS 770)
- Changed in 2007 (TRS 946)
- Changed in 2007 (TRS 950)
- Changed in 2021

### Sex
- All

### Age
- Also recommended for children

### Therapeutic alternatives
- The recommendation is for this specific medicine

### Patent information
- Patents have expired in most jurisdictions
- Read more about patents.

### Wikipedia
- [Valproic acid](https://en.wikipedia.org/wiki/Valproic_acid)

### DrugBank
- [Valproic acid](https://www.drugbank.ca/drugs?name=valproic_acid)

#### Expert Committee recommendation

The Expert Committee recognized the serious risks associated with the use of valproic acid in pregnant women and in females of child-bearing potential. While most of the evidence and regulatory measures described in the application are from Europe, the risks with valproate when prescribed to women and girls of child-bearing potential are equally relevant globally. Sodium valproate is currently listed as an essential medicine for use in the treatment of epilepsy and bipolar disorder, indications for which it has regulatory approval. Furthermore, valproic acid is recommended for the management of epilepsy and bipolar disorder in the WHO mhGAP intervention guide. These guidelines also include a strong recommendation to avoid the use of valproic acid in women of child-bearing age. The Committee considered that inclusion of a cautionary note with the listings of valproic acid to indicate that use should be avoided in pregnant women and females of child-bearing potential was appropriate, although it is aware the EML does not replace prescribing information issued by national medicine regulatory authorities. The Committee did not recommend transferring the listing of valproic acid from the core to the complementary list. The Committee considered doing so may have negative implications for access to valproic acid and undermine its important role in the management of epilepsy and bipolar disorder, particularly in resource-constrained settings, where access to valproate and alternative treatments is limited. The Committee supported the need for patient and prescriber education on the risks and appropriate use of valproic acid, including its use for off-label indications, but considered this to be a responsibility of the relevant national decision-makers. The Committee recommended the following note be included with the listings for valproic acid on the EML and EMLc: “Avoid use in pregnancy and in women and girls of child-bearing potential unless alternative treatments are ineffective or not tolerated, because of the high risk of
birth defects and developmental disorders in children exposed to valproate in the womb.