



1 May 2020

Medicine Supply Alert Notice

Valproate semisodium (Depakote®) 250mg and 500mg tablets

Priority: Level 2* update to MSAN (2020)13

Valid until: mid May 2020

Issue

1. Depakote® 250mg and 500mg tablets are out of stock until mid May 2020.
2. Limited supplies of Depakote® tablets are available from parallel import companies (see information below).
3. Syonell® (valproate semisodium) tablets are in stock and able to support the market during this time.
4. Belvo® (valproate semisodium) tablets are in stock and able to partially support the market during this time.
5. NOTE: information in this MSAN **only applies to the use of valproate semisodium in licensed indications** i.e. the treatment of manic episodes in bipolar disorder when lithium is contraindicated or not tolerated. The continuation of treatment after manic episodes could be considered in patients who have responded to valproate semisodium for acute mania.

Advice and Actions

6. For patients with insufficient supplies until the resupply date, clinicians should consider prescribing valproate semisodium tablets generically to enable any brand to be dispensed (see supporting information below).

Additional Information

7. The MHRA has confirmed that brand prescribing of valproate tablets for treatment of manic episodes in bipolar disorder (sole licensed indication) is not necessary as per NICE clinical guideline for Bipolar Disorder (CG185): <https://www.nice.org.uk/guidance/cg185>.
8. Dose changes and additional monitoring are not required when switching between different brands of valproate semisodium tablets when used for bipolar disorder.
9. See the Summary of Product Characteristics (SPCs) below for further information:
 - Syonell® tablets <https://www.medicines.org.uk/emc/search?q=%22Syonell%22>
 - Belvo® tablets <https://www.medicines.org.uk/emc/search?q=%22belvo%22>
 - Depakote tablets®* <https://www.medicines.org.uk/emc/search?q=depakote>
*Depakote SPC has not yet been updated to reflect that brand prescribing of valproate semisodium tablets is not necessary when used for treatment of manic episodes in bipolar disorder
10. Pregnancy Prevention Programme (PPP)
 - Valproate must not be used in any woman or girl able to have children unless there is a pregnancy prevention programme (PPP) in place. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant.
 - These regulatory measures, announced following a large-scale review of the risk in 2018, also include a ban on the use of valproate for migraine or bipolar disorder during pregnancy,

and a ban on the use of valproate to treat epilepsy during pregnancy unless there is no other effective treatment available.

- Healthcare professionals who seek to prescribe valproate to their female patients must make sure they are enrolled in the PPP. This includes the completion of a signed risk acknowledgement form when their treatment is reviewed by a specialist, at least annually.
- Further information is available via <https://www.gov.uk/guidance/valproate-use-by-women-and-girls>

11. Patient reassurance may be needed due to differences in packaging of each brand.

12. The following parallel importers have currently confirmed availability of Depakote® tablets (please note, there may be other companies that can also source supplies):

- Depakote® 250mg tablets
NG Ltd – order via main wholesalers
Sigma – order direct from company
Nupharm – order via Phoenix
- Depakote® 500mg tablets
Sigma – order direct from company
Nupharm – order via Phoenix

Enquiries

13. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to PharmacyTeam@gov.scot (primary care) or NSS.NHSSMedicineShortages@nhs.net (secondary care).