NHS Circular:
MSAN (2019) 31

Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
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24 December 2019

Medicine Supply Alert Notice

Convulex® (Valproic acid) 150mg, 300mg and 500mg capsules

Priority: Level 3*
Valid until: 30 April 2020

Issue

1. There is a supply issue affecting all strengths of Convulex® (valproic acid) capsules due to a pack size update (switching from 100 to 30 capsules), which has led to a delay of the next supply until April 2020.

2. The following presentations of Convulex® (valproic acid) capsules will be out of stock:
   - Convulex® 150mg capsules – anticipated out of stock week commencing 30 December 2019
   - Convulex® 300mg capsules – anticipated out of stock week commencing 10 February 2020
   - Convulex® 500mg capsules – currently out of stock.

3. Unlicensed imports of Convulex® (valproic acid) are available from specialist unlicensed importers.

Advice and Actions

4. Convulex® is the only valproic acid product licensed for the treatment of generalised, partial or other epilepsy in children and adults. Alternative valproic acid preparations are licensed for manic episodes in bipolar when lithium is contraindicated or not tolerated.

5. Valproate is available in the UK in three forms: sodium valproate, valproic acid and semi-sodium valproate. Both semi-sodium valproate and sodium valproate are metabolised to valproic acid, which is responsible for the pharmacological activity of all three preparations. The risk of switching between valproic acid and sodium valproate preparations is low, and less than the risk of abrupt discontinuation of the drug altogether. Patients should be advised that there is a small risk of breakthrough seizures and that if these occur, they should contact their GP or specialist.

6. All healthcare professionals in primary, secondary or specialist healthcare services who prescribe and supply valproic acid capsules should work together to:
   - ensure that specialist neurology teams support colleagues in primary care if further advice is required;
   - take the opportunity this shortage offers to consider, with specialist input and where feasible, changing patients to a different antiepileptic drug (AED) other than valproic acid or sodium valproate;
   - consider prescribing unlicensed Convulex® capsules where changing to a different AED is not appropriate *(these are interchangeable to the licensed version, so require no dosing adjustments;*
   - consider switching patients to a different AED as set out in paragraph 7 if prescribing unlicensed Convulex® capsules is not considered appropriate or feasible:
   - ensure patients understand that although there is a small risk of breakthrough seizures when switching between valproic acid and sodium valproate preparations, it is less than the risk of abrupt discontinuation of the drug altogether; and
   - make sure all female patients who continue treatment containing valproate are enrolled in the pregnancy prevention programme (PPP).

***https://nhsnss.org/media/3874/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.docx**

7. Alternative products include:

Sodium valproate - *Valproic acid (Convulex®) capsules have a one to one dose relationship with products containing sodium valproate, so requires no dosing adjustments.*

- Sodium valproate tablets (100mg – Epilim crushable®)
- Sodium valproate gastro-resistant tablets* (200 and 500mg – Epilim®). Also available as a non-branded (generic) product
- Sodium valproate modified-release tablets (200, 300 and 500mg – Epival CR®, Epilim Chrono®)
- Sodium valproate modified-release capsules (150 and 300mg – Episenta®)
- Sodium valproate oral solution* (200mg/5ml – Epilim®)
- Sodium valproate modified-release granules (50, 100, 250, 500, 750 and 1000mg – Epilim Chronosphere®)

Valproic acid tablets (unlicensed for the treatment of generalised, partial or other epilepsy in children and adults) - *Valproic acid tablets are interchangeable, so requires no dosing adjustments, however not all alternative preparations are available in the same strength as Convulex® capsules.*

- Belvo® 250mg gastro-resistant tablets
- Belvo® 500mg gastro-resistant tablets
- Depakote® 250mg gastro-resistant tablets
- Depakote® 500mg gastro-resistant tablets

8. Please refer to the Summary of Product Characteristics (SPC) of the selected product to make sure the correct dose frequency is prescribed. Patients should be counselled on use of the new product to ensure they take the correct dose and to report any problems with side effects or seizure control after the switch.

Additional Information

9. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board local governance procedures. Please see the links below for further information:
   - Prescribing unlicensed medicines, General Medical Council (GMC);
   - The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA); and
   - Professional guidance for the procurement and supply of specials, Royal Pharmaceutical Society (RPS).

Enquiries

10. Any enquiries should be directed to – PharmacyTeam@gov.scot or NSS.NHSSMedicineShortages@nhs.net