



30 May 2024

Medicine Supply Alert Notice

Nortriptyline 10mg/5ml and 25mg/5ml oral solution sugar-free

Priority: Level 2*

Valid until: Products are being discontinued

Issue

1. Nortriptyline 10mg/5ml oral solution sugar-free has been discontinued; all supplies have now been exhausted.
2. Nortriptyline 25mg/5ml oral solution sugar-free will be discontinued from 1st November 2024.
3. Nortriptyline 10mg and 25mg tablets remain available and can support increased demand.
4. Amitriptyline 10mg/5ml and 25mg/5ml oral solution sugar-free remain available and can support increased demand.
5. Unlicensed specials of nortriptyline 10mg/5ml and 25mg/5ml oral suspension sugar-free are available, lead times vary.

Advice and Actions

6. Where are insufficient supplies of nortriptyline 10mg/5ml or 25mg/5ml oral solution sugar-free and patients do not have swallowing difficulties consider prescribing:
 - nortriptyline 10mg or 25mg tablets.
7. Where patients have swallowing difficulties or enteral feeding tubes consider:
 - prescribing nortriptyline 10mg or 25mg tablets, counselling patients on crushing tablets and dispersing in water (off-label; see Additional information); or
 - consider prescribing unlicensed specials of nortriptyline oral suspension (see Additional information); or
 - if the above options are not appropriate, consider prescribing amitriptyline 10mg/5ml or 25mg/5ml oral solution sugar-free, ensuring patients are counselled on the change in medicine, dose, and to report any side effects to their prescriber (see Additional information section);
 - other antidepressants can be considered if amitriptyline is not suitable.

Additional Information

8. Nortriptyline is licensed for use in depression and is used in practice for neuropathic pain (off-label).

*<https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf>

9. Nortriptyline is the principle active metabolite of amitriptyline and has similar actions to that of amitriptyline. It is less sedating compared to amitriptyline.

Advice on switching to amitriptyline oral solution

10. The clinical alternative to nortriptyline is amitriptyline in patients who have not tried amitriptyline previously. Amitriptyline is licensed for depression and neuropathic pain. Amitriptyline 60mg is approximately equivalent to nortriptyline 50mg. If the clinical decision is made to switch from nortriptyline to amitriptyline, a direct switch, i.e. stopping one medicine and then starting the new medicine the following day, is normally possible.
11. There may be an increased risk of anticholinergic burden when switching patients from nortriptyline to amitriptyline. Monitor for anticholinergic side effects such as dry mouth, constipation, urinary retention.

Advice on crushing nortriptyline oral tablets

12. Nortriptyline tablets can be crushed and dispersed in water for administration in patients with swallowing difficulties or enteral feeding tubes (off-label). Note: if administered directly into the jejunum using an NJ, PEJ, PEGJ tube then monitor for increase in side effects.

Advice on neuropathic pain

13. For neuropathic pain, [NICE CG173](#) recommends amitriptyline, duloxetine, gabapentin or pregabalin as treatment options in adults. Specialist advice may be needed if the patient has tried these options already or are under a specialist team.

Guidance on ordering and prescribing unlicensed medicines

14. The following Specials manufacturers have confirmed they can manufacture nortriptyline 10mg/5ml and/or 25mg/5ml oral suspension sugar-free (please note there may be other companies that can also manufacture supplies):

- | | |
|------------------------|-----------------------|
| • Eaststone | 10mg/5ml |
| • Target Healthcare | 10mg/5ml and 25mg/5ml |
| • Nova Laboratories | 10mg/5ml and 25mg/5ml |
| • IPS Pharma | 10mg/5ml and 25mg/5ml |
| • Rokshaw Laboratories | 10mg/5ml and 25mg/5ml |

15. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes.
16. Please see the links below for further information:
- [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
 - [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC).

Links to further information

- [SmPC Nortriptyline 10mg/5ml oral solution](#)
- [SmPC Nortriptyline 25mg/5ml oral solution](#)
- [BNF: Tricyclic and related antidepressant drugs](#)
- [BNF Nortriptyline](#)
- [SmPC Amitriptyline oral solution BNF Amitriptyline](#)

Specialist Pharmacy Service (SPS) website

17. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the [SPS website](#). Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
18. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

Enquiries

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