



16 October 2024

Medicine Supply Alert Notice

Trandate® (labetalol) 50mg tablets

Priority: Level 2*

Valid until: product to be discontinued from July 2025

Issue

1. Trandate® (labetalol) 50mg tablets will be discontinued from July 2025.
2. Alternative low dose beta-blockers remain available. Where these are not suitable, UK manufactured specials of labetalol 50mg/5ml oral suspension may be sourced, lead times vary.

Advice and Actions

3. Prescribers should not initiate new patients on Trandate 50mg tablets and should review existing patients to establish the reason for use of a low dose, and where appropriate, consider:
 - prescribing an alternative oral beta-blocker (see supporting information below); or
 - if the above option is not considered suitable, consider prescribing UK manufactured specials of labetalol 50mg/5ml oral suspension, where licensed alternatives are not appropriate. Prescribers should work with local Pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see additional information below).

Additional Information

Clinical information

4. Labetalol 50mg tablets are licensed for the treatment of:
 - Mild, moderate and severe hypertension
 - Hypertension in pregnancy
 - Angina pectoris with existing hypertension
5. According to the product licence, a low dose of 50mg twice a day may be used in the elderly. In addition, low doses may also be used in patients with liver impairment. For all other indications, including hypertension in pregnancy, the starting dose of labetalol for adults is 100mg twice a day, increased by increments of 100mg twice a day as needed.
6. When selecting an alternative beta-blocker and dose, factors to be considered include indication, licensed dose range, age, co-morbidities, local guidance and formulary recommendations.

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

7. NICE CKS provides prescribing advice (including usual starting and maintenance doses) for beta-blockers in hypertension and angina.

Guidance on ordering and prescribing unlicensed imports

8. The following Specials manufacturers have confirmed they can manufacture labetalol 50mg/5ml oral suspension sugar-free (please note there may be other companies that can also manufacture supplies):
- Eaststone
 - IPS Pharma
 - Rokshaw Laboratories
 - Target Healthcare
9. 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. 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: Trandate® \(labetalol\) 50mg tablets](#)
- [BNF: Beta- adrenoceptor blocking drugs](#)
- [NICE CKS: Hypertension- Beta-blockers](#)
- [NICE CKS: Angina- Beta Blockers](#)

Specialist Pharmacy Service (SPS) website

10. 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.
11. 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

12. 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).