



# Medicine Supply Notification

MSN/2024/101

Trandate<sup>®</sup> (labetalol) 50mg tablets

Tier 2 – medium impact\*

Date of issue: 07/10/2024

Link: [Medicines Supply Tool](#)

## Summary

- Trandate<sup>®</sup> (labetalol) 50mg tablets will be discontinued from July 2025.
- 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.

## Actions Required

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 supporting information below).

## Supporting information

### Clinical information

Labetalol 50mg tablets are licensed for the treatment of:

- Mild, moderate and severe hypertension
- Hypertension in pregnancy
- Angina pectoris with existing hypertension

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.

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.

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

\*Classification of Tiers can be found at the following link:

<https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>

## Guidance on ordering and prescribing unlicensed imports

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

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust 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)

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:

Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select:

- Labetalol 50mg/5ml oral suspension (special order)

Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: “**special order**”.

## Links to further information

[SmPC: Trandate® \(labetalol\) 50mg tablets](#)

[BNF: Beta- adrenoceptor blocking drugs](#)

[NICE CKS: Hypertension- Beta-blockers](#)

[NICE CKS: Angina- Beta Blockers](#)

## Enquiries

If you have any queries, please contact [DHSCmedicinesupplyteam@dhsc.gov.uk](mailto:DHSCmedicinesupplyteam@dhsc.gov.uk).