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Medicine Supply Notification: Amiodarone 100mg and 200mg tablets

Tier 2 – medium impact Date of issue: 20/10/2025

<u>Medicines Supply Tool – SPS - Specialist Pharmacy Service – The first stop for professional</u> medicines advice

Summary

- Amiodarone 100mg and 200mg tablets are in limited supply until w/c 17 November 2025.
- Amiodarone suspension remains available (Specials).
- Unlicensed imports of amiodarone 100mg and 200mg tablets have been sourced (lead times vary).
- Alternative antiarrhythmics agents remain available

Actions Required

Clinicians should not initiate new patients on amiodarone tablets (other than those with critical arrhythmias – see below) until the supply issue has resolved.

Where patients have insufficient supply to last until the resupply date, clinicians should liaise with specialists to determine whether amiodarone continues to be the most suitable therapy and discuss alternative management options, if appropriate. This should include a review of those not in sinus rhythm despite taking amiodarone for rhythm control and any patient with atrial fibrillation (AF) / atrial flutter prescribed amiodarone for rate control.

Reserve any remaining supplies of amiodarone tablets for patients in whom specialists have advised that amiodarone is the most appropriate therapy (such as in ventricular tachycardia).

Where tablets are unavailable, consider prescribing amiodarone suspension which remains available (Specials) (see Supporting information).

Advice should be sought from specialists on alternative management options if the above options are not considered appropriate.

Additionally in secondary care, consider reserving any remaining supplies of amiodarone 100mg tablets for use in neonatal and paediatric patients to ensure a continuous supply. Where supplies are unavailable, discuss with specialist paediatric cardiologists, pharmacy and nursing teams for consideration of alternative treatments.



Supporting information

Clinical Information

Amiodarone is only indicated for the treatment of severe rhythm disorders not responding to other therapies or when other treatments cannot be used. Treatment should be initiated and normally monitored only under hospital or specialist supervision. Primary care is recommended to only prescribe amiodarone if initiated in secondary care and, ideally, where there is a shared care arrangement in place. Amiodarone is not recommended for rate control in AF / atrial flutter

Guidance on ordering and prescribing unlicensed medicines.

The following companies have confirmed they can manufacture amiodarone suspension (Specials) in various strengths (including 100mg/5ml and 200mg/5ml) and pack sizes (please note there may be other companies that can also manufacture supplies).

Please contact the companies directly to understand specific product availability and lead times:

- Eaststone
- IPS Pharma
- Nova Laboratories
- Rokshaw
- Syrimed
- Target Healthcare

The following specialist importer has confirmed they can source unlicensed amiodarone 100mg and 200mg tablets (please note there may be other companies that can also source supplies):

Mawdsley's Unlicensed

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and HSC Trust or local governance procedures. Unlicensed medicines do not undergo any central quality assessment or suitability evaluation. Therefore, any medicine 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) The supply of unlicensed medicinal products special GN14.pdf
- Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society specials-professional-guidance.pdf
- Prescribing unlicensed medicines, General Medical Council (GMC) <u>Prescribing unlicensed</u> medicines - professional standards - 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 HS21 prescription that an unlicensed product is required, with the following wording: "special order"

Information produced by DHSC and disseminated by SPPG Pharmacy and Medicines Management Team. For most up-to-date information, visit Shortages Information - Business Services Organisation (BSO) Website (hscni.net)



Links to further information

- SmPC amiodarone tablets <u>Amiodarone Hydrochloride 200mg Tablets Summary of Product Characteristics (SmPC) (emc) | 101141</u>
- BNF amiodarone Amiodarone hydrochloride | Drugs | BNF | NICE
- BNF arrythmias <u>Arrhythmias | Treatment summaries | BNF | NICE</u>