




ATC codes: **C01BD01**

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| Indication | Cardiac arrhythmia ICD11 code: BC8Z |
| INN | Amiodarone |
| Medicine type | Chemical agent |
| List type | Complementary |
| Formulations | Parenteral > General injections > IV: 50 mg per mL in 3 ampoule (hydrochloride) Oral > Solid: 100 mg (hydrochloride) ; 200 mg (hydrochloride) ; 400 mg (hydrochloride) |
| EML status history | First added in 2009 (TRS 958) |
| Sex | All |
| Age | Adolescents and adults |
| Therapeutic alternatives | The recommendation is for this specific medicine |
| Patent information | Patents have expired in most jurisdictions Read more about patents.  |
| Wikipedia | Amiodarone  |
| DrugBank | Amiodarone  |

Summary of evidence and Expert Committee recommendations

Following a request from the Expert Committee in 2007, an application was prepared by the WHO Collaborating Centre for Evidence-Based Research Synthesis and Guideline Development in Reproductive Health for the inclusion of amiodarone; tablets 100 mg, 200 mg, 400 mg and 50 mg/ml vials and ampoules, for both the acute and chronic treatment of supraventricular and ventricular arrhythmias. The Committee noted that the efficacy and safety data presented in the application were derived from RCTs and systematic reviews and generally supported the view that amiodarone is both effective and safe for use in arrhythmic disorders, but did not support the use of amiodarone in the routine treatment of chronic heart failure. The Committee also noted the role of amiodarone in selected acute care settings. Amiodarone is recommended in both the PALS and ACLS guidelines for cardiac arrest with pulseless ventricular tachycardia or ventricular fibrillation (unresponsive to defibrillation, cardiopulmonary resuscitation and vasopressor administration). It is also recommended in the PALS guidelines for supraventricular tachycardia (unresponsive to vagal manoeuvres and adenosine). The Committee noted the recommendation that amiodarone treatment should be initiated by a specialist and baseline investigations performed before treatment begins (chest X-ray, pulmonary, thyroid and liver function tests). Thereafter, longitudinal assessment of thyroid and liver function is required and other specialist investigations may be necessary during the course of treatment. Safe use also requires vigilant assessment of concomitant drug-drug interactions with warfarin and digoxin in particular. Based on the evidence presented in the application the Committee recommended inclusion of amiodarone on the Complementary Model List. In the absence of evidence of effectiveness and safety of the medicine in children, the Committee did not add it to the EMLC, but requested further review of the antiarrhythmics as used in children.

