

ISSUED: 25 AUGUST 2010

PRESS RELEASE

NICE guidance gives people living with atrial fibrillation more treatment options

In guidance published today NICE recommends the use of dronedarone as a second-line treatment in people with additional cardiovascular risk factors whose atrial fibrillation (AF) has not been controlled by first-line therapy (usually including beta-blockers). The guidance recommends dronedarone as an option for the treatment of non-permanent atrial fibrillation **only** in people:

- whose atrial fibrillation is not controlled by first-line therapy (usually including beta-blockers), that is, as a second-line treatment option, **and**
- who have at least one of the following cardiovascular risk factors:
 - hypertension requiring drugs of at least two different classes
 - diabetes mellitus
 - previous transient ischaemic attack, stroke or systemic embolism
 - left atrial diameter of 50 mm or greater
 - left ventricular ejection fraction less than 40% (noting that the summary of product characteristics [SPC] does not recommend dronedarone for people with left ventricular ejection fraction less than 35% because of limited experience of using it in this group) **or**
 - age 70 years or older, **and**
- who do not have unstable New York Heart Association (NYHA) class III or IV heart failure¹.

¹ The New York Heart Association classification of heart failure relates symptoms to everyday activities and the patient's quality of life. Class III indicates a marked limitation of physical activity and class IV indicates being unable to carry out any physical activity without discomfort.

In recommending the use of dronedarone as a treatment option for some people with AF, the independent Appraisal Committee noted comments from patients and clinical experts received during consultation on the draft guidance that all current anti-arrhythmic drugs have side effects which can have a significant impact on quality of life with long term use. It heard from patient experts that some people with atrial fibrillation might prefer to take dronedarone because it has fewer side effects, despite it being less effective than other antiarrhythmic drugs in preventing recurrence of atrial fibrillation. The committee also accepted evidence that the drug did not lead to an increase in the risk of mortality, unlike the anti-arrhythmics with which it was compared.

Atrial fibrillation is one of the most common heart rhythm disturbance conditions. It can cause symptoms such as palpitations and tiredness and is associated with an increased risk of thrombus (blood clot) formation and thromboembolism including ischaemic strokes. The prevalence of AF increases with age and in the UK nearly 50,000 new cases of AF are diagnosed each year. Standard baseline therapy for AF may include drugs to maintain sinus rhythm, where beta-blockers are usually the first choice.

Ends

For more information call the NICE press office on 0845 003 7782 or 07775 583 813.

Notes to Editors

About the guidance

1. Atrial fibrillation (AF) is one of the most common heart rhythm disturbance conditions. It can cause symptoms such as palpitations and tiredness.
2. AF is associated with an increased risk of thrombus (blood clot) formation and thromboembolism including ischaemic strokes.
3. The prevalence of AF increases with age with a prevalence of 0.5% at age 50-59 years increasing to almost 9% at age 80-89 years. In the UK, more than 46,000 new cases of AF are diagnosed each year.
4. Standard baseline therapy for AF may include drugs to maintain sinus rhythm, where beta-blockers are usually the first choice. Where standard baseline therapy with a beta-blocker is ineffective, contraindicated or not tolerated, second line therapy is chosen according to various factors including whether the person has structural heart abnormalities. Either flecainide or sotalol may be chosen if there are no structural abnormalities and amiodarone may be used in people with structural heart disease.
5. The cost per day based on the recommended dosage of dronedarone would be £2.25. The cost of an existing comparator drug, amiodarone, is approximately £0.05 per day.
6. The guidance is available on the NICE website at www.nice.org.uk/guidance/TA197

About NICE

1. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
2. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments, procedures and medical technologies within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.