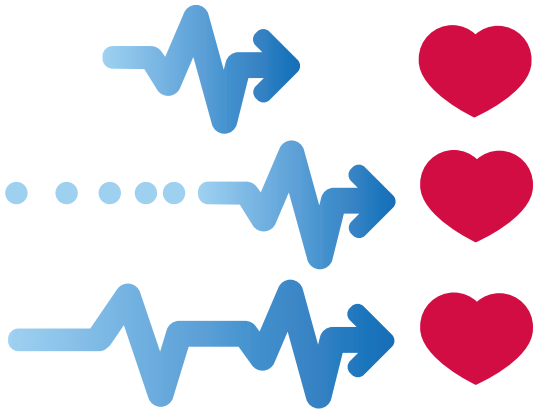
ATRIAL FIBRILLATION (AF) CONSUMER MEDIA FACTSHEET

1

AF is the most common sustained heart rhythm disorder, affecting approximately **70 million people worldwide** with **one in four adults** over the age of 40 developing the condition in their lifetime.[1,2]

AF can cause your heart to beat...

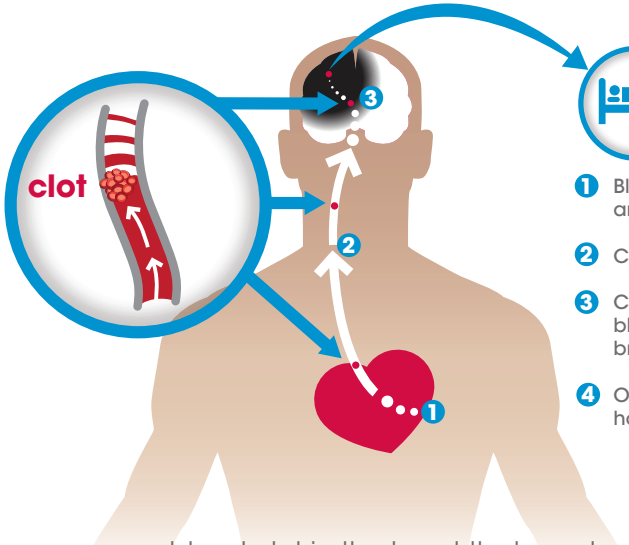


Too **slowly**

Too **quickly**

Irregularly

2

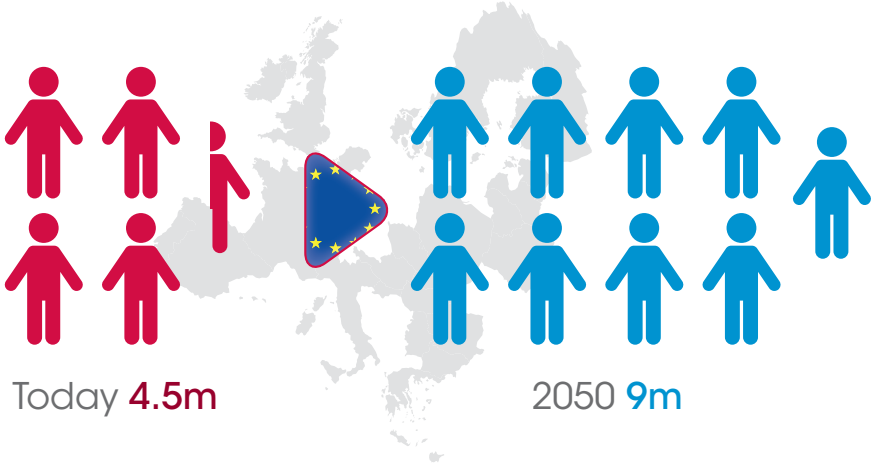


1. Blood pools in the heart and large clots can form
2. Clots can travel to the brain
3. Clots can block the bloodflow to areas of the brain
4. Often leads to hospitalisation or death

AF can cause a blood clot in the heart that can travel up to the brain vessels, blocking it and causing a stroke.

3

In **Europe** the prevalance is projected to be more than **DOUBLE** by **2050**.[3,4]



Today **4.5m**

2050 **9m**

4

In addition to social costs, **quality of life is worse** in patients with AF versus other cardiac conditions.[5,6]

1. National Heart Blood & Lung Institute Diseases & Conditions Index. Types of atrial fibrillation - http://www.nhlbi.nih.gov/health/dci/Diseases/af/af_types.html (last viewed 14 March 2011). **2.** Stewart S, *et al. Heart* 2004; **90**:286-92; Lloyd-Jones DM *et al. Circulation* 2004; **110**:1042-6. **3.** Miyasaka Y, *et al. Circulation* 2006; **114**:119-125. **4.** Fuster V, *et al. Circulation* 2006;**114**:e257-e354 **5.** Laurence GM *et al.* Europace (2010) **12**, 634–642 **6.** SPEAK about AF Survey. 2011 Boehringer Ingelheim GmbH. Dorian P, *et al. J Am Coll Cardiol* 2000; **36**: 1303–9.

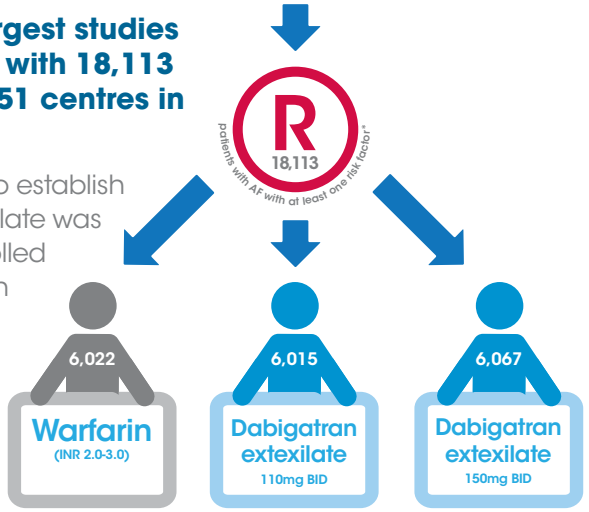
DABIGATRAN ETEXILATE CONSUMER MEDIA FACTSHEET

1

RE-LY® is one of the largest studies ever conducted in AF, with 18,113 patients enrolled in 951 centres in 44 countries.[1,2]

- The main objective was to establish whether dabigatran etexilate was as effective as well-controlled warfarin for the prevention of stroke and systemic embolism.

*Previous stroke or transient ischemic attack, a left ventricular ejection fraction of less than 40%, New York Heart Association class II or higher heart-failure symptoms within six months before screening, age of at least 75 years, or an age of 65 to 74 years plus diabetes mellitus, hypertension, or coronary artery disease.



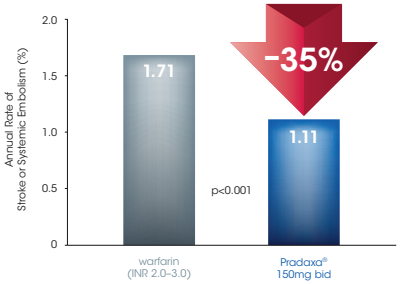
Patient follow-up = min 1 year – max 3 years

2

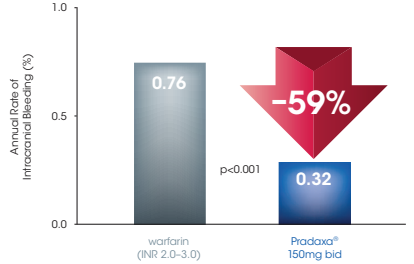
Dabigatran etexilate versus warfarin – results from the RE-LY trial.*

Dabigatran etexilate 150mg bid:

Superior stroke prevention compared to well-controlled warfarin, reducing the risk of stroke and systemic embolism by 35%



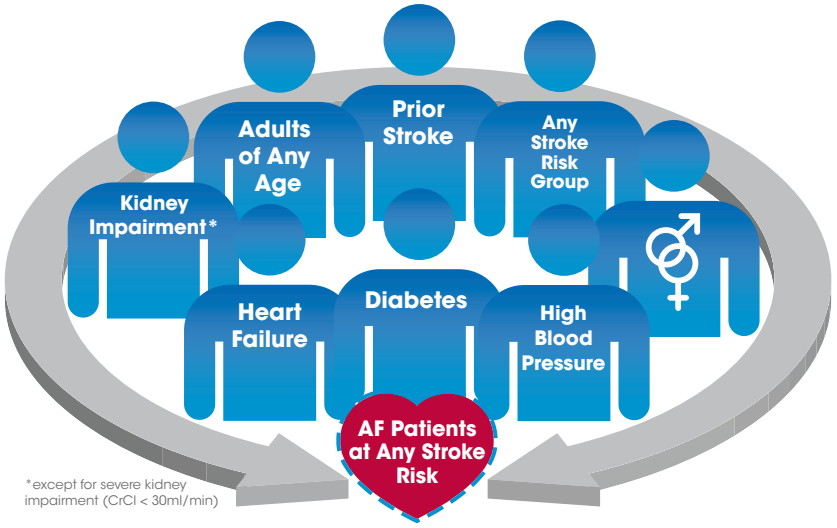
Provides significant reductions in intracranial bleeding (-59%) and a reduced risk of total (-9%) and life-threatening (-20%) bleeding versus well-controlled warfarin



Dabigatran etexilate 110mg bid is as effective as warfarin in reducing the risk of stroke and systemic embolism in patients with AF and significantly reduces major (-20%), total (-22%), life threatening (-33%)and intracranial bleeding (-70%).[2–4]

*The results of RE-LY® were demonstrated via a PROBE (prospective, randomized, open-label with blinded endpoint evaluation) trial design, comparing two fixed doses of the oral direct thrombin inhibitor dabigatran etexilate (110mg and 150mg bid) each administered in a blinded manner, with open label warfarin.

3



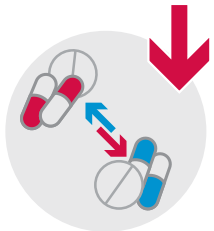
*except for severe kidney impairment (CrCl < 30ml/min)

Dabigatran etexilate protects a wide range of AF patients from stroke.[2–9]

4

Both doses of dabigatran etexilate (150mg and 110mg twice daily) have **an excellent safety profile** with similar tolerability to well controlled warfarin, except for dyspepsia.*[2,10–14]

Does not require routine coagulation monitoring or dose titration



Low potential for drug-drug interactions

No food-drug interactions and dosing independent of meals or dietary restrictions

* a common digestive disorder with symptoms such as abdominal discomfort

1. Ezekowitz MD, Connolly S, Parekh A, *et al. Am Heart J* 2009;**157**: 805-10 **2.** Connolly SJ *et al. N Engl J Med* 2009;**361**:1139–51 **3.** Connolly SJ, *et al. N Engl J Med* 2010;**363**(19): 1875-1876; **4.** FDA Advisory Committee Briefing Document, September 2010. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisory Committee/UCM226009.pdf **5.** Flaker GC, *et al.* ACC, 3rd April 2011; **6.** Diener, HC, *et al. Lancet Neurol* 2010; **9**: 1157–63; **7.** Oldgren J, *et al.* ACC, 15th March 2010; **8.** Lars Wallentin, *et al.*, on behalf of the RE-LY® investigators. *Lancet* 2010; **376**: 975-83; **9.** Eikelboom JW, *et al. Circulation* published online May 16, 2011; DOI: 10.1161/CIRCULATIONAHA.110.00474. **10.** Stangier J, *et al. Br J Pharmacol* 2007;*64*:292-303. **11.** Pradaxa, Summary of Product Characteristics, 2008. **12.** Stangier *J. Clin Pharmacokinet* 2008;47:285–95. **13.** Blech S, Ebner T, Ludwig-Schwellinger E, *et al. Drug Metab Dispos* 2008;**36**:386–99. **14.** Stangier J, *et al. Am J Cardiovasc Drugs* 2009;**9**:59-68.