We Claim:

1. Use of dabigatran etexilate, optionally in the form of a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for the prevention of stroke in patients suffering from atrial fibrillation wherein the patient has ~~at least one~~ a risk factor for major bleeding events, which is a creatinine clearance less than 50 mL/min, and wherein the use comprises the b.i.d. administration of 110 mg dabigatran etexilate, optionally in the form of a pharmaceutically acceptable salt thereof.

2. The use according to claim 1, wherein the patient has one additional ~~at least two~~ risk factors for major bleeding events.

3. The use according to claim 1 or 2, wherein the patient having one additional risk factor for major bleeding events is selected from

- being an age of 75 years or greater;
- having a history of earlier bleeding events;
- alcohol/drug abuse;
- concomitant diseases like anemia, cancer, stroke, transient ischemic attacks, MI, hypertension, heart failure/cardiomyopathy, ischemic heart disease, diabetes, hepatic failure, or peptic ulcer disease; and
- concomitant risks for injury like risk for falls, cognitive impairment or surgery during index hospitalization.

4. The use according to claim 1 or 2, wherein the patient having two or more additional risk factors for major bleeding events is selected from

- being an age of 75 years or greater;
- having a history of earlier bleeding events;
- alcohol/drug abuse,
- concomitant diseases like anemia, cancer, stroke, transient ischemic attacks, MI, hypertension, heart failure/cardiomyopathy, ischemic heart disease, diabetes, hepatic failure, or peptic ulcer disease; and
- concomitant risks for injury like risk for falls, cognitive impairment or surgery during index hospitalization.

5. The use according to claim 1 or 2, wherein the patient being 75 years or greater and having one or more additional risk factors for major bleeding events is selected from

- having a history of earlier bleeding events;
- alcohol/drug abuse,
- concomitant diseases like anemia, cancer, stroke, transient ischemic attacks, MI, hypertension, heart failure/cardiomyopathy, ischemic heart disease, diabetes, hepatic failure, or peptic ulcer disease; and
- concomitant risks for injury like risk for falls, cognitive impairment or surgery during index hospitalization.

6. The use according to claim 1 or 2, wherein the patient having a history of earlier bleeding events and having one or more additional risk factors for major bleeding events is selected from

- being an age of 75 years or greater;
- alcohol/drug abuse,
- concomitant diseases like anemia, cancer, stroke, transient ischemic attacks, MI, hypertension, heart failure/cardiomyopathy, ischemic heart disease, diabetes, hepatic failure, or peptic ulcer disease; and
- concomitant risks for injury like risk for falls, cognitive impairment or surgery during index hospitalization.

7. The use according to any one of claims 1 to 6, wherein the patient has a creatinine clearance of more than 30 mL/min.

~~3. The use according to claim 1 or 2, wherein the risk factor for major bleeding events includes an age of 75 years or greater.~~

~~4. The use according to one of claims 1, 2 or 3, wherein the risk factor for major bleeding events includes a history of earlier bleeding events.~~

~~5. The use according to one of claims 1 to 4, wherein the risk factor for major bleeding events includes a reduced creatinine clearance less than 80 mL/min.~~

~~6. The use according to claim 5, wherein the risk factor for major bleeding events includes reduced creatinine clearance less than 50 mL/min.~~

8. Dabigatran etexilate, optionally in the form of a pharmaceutically acceptable salt thereof for use in preventing stroke in a patient suffering from atrial fibrillation, wherein 110 mg of dabigatran etexilate, optionally in the form of a pharmaceutically acceptable salt thereof are administered b.i.d. to a patient who has a risk factor for major bleeding events, which is a creatinine clearance less than 50 mL/min.

9. Dabigatran etexilate, optionally in the form of a pharmaceutically acceptable salt thereof for use in preventing stroke in a patient suffering from atrial fibrillation, according to claim 8 wherein the patient having one additional risk factor for major bleeding events.

10. Dabigatran etexilate, optionally in the form of a pharmaceutically acceptable salt thereof for use in preventing stroke in a patient suffering from atrial fibrillation according to one of the claims 8 or 9, wherein the patient having one additional risk factor for major bleeding events is selected from

- being an age of 75 years or greater;
- having a history of earlier bleeding events;
- alcohol/drug abuse;
- concomitant diseases like anemia, cancer, stroke, transient ischemic attacks, MI, hypertension, heart failure/cardiomyopathy, ischemic heart disease, diabetes, hepatic failure, or peptic ulcer disease; and
- concomitant risks for injury like risk for falls, cognitive impairment or surgery during index hospitalization.

11. Dabigatran etexilate, optionally in the form of a pharmaceutically acceptable salt thereof for use in preventing stroke in a patient suffering from atrial fibrillation according to one of the claims 8 or 9, wherein the patient having two or more additional risk factors for major bleeding events is selected from

- being an age of 75 years or greater;
- having a history of earlier bleeding events;
- alcohol/drug abuse,
- concomitant diseases like anemia, cancer, stroke, transient ischemic attacks, MI, hypertension, heart failure/cardiomyopathy, ischemic heart disease, diabetes, hepatic failure, or peptic ulcer disease; and

- concomitant risks for injury like risk for falls, cognitive impairment or surgery during index hospitalization.

12. Dabigatran etexilate, optionally in the form of a pharmaceutically acceptable salt thereof for use in preventing stroke in a patient suffering from atrial fibrillation according to one of the claims 8 or 9, wherein the patient being the age of 75 years or greater and having one or more additional risk factor for major bleeding events is selected from

- having a history of earlier bleeding events;
- alcohol/drug abuse,
- concomitant diseases like anemia, cancer, stroke, transient ischemic attacks, MI, hypertension, heart failure/cardiomyopathy, ischemic heart disease, diabetes, hepatic failure, or peptic ulcer disease; and
- concomitant risks for injury like risk for falls, cognitive impairment or surgery during index hospitalization.

13. Dabigatran etexilate, optionally in the form of a pharmaceutically acceptable salt thereof for use in preventing stroke in a patient suffering from atrial fibrillation according to one of the claims 8 or 9, wherein the patient having history of earlier bleeding events and having one or more additional risk factor for major bleeding events is selected from

- being an age of 75 years or greater;
- alcohol/drug abuse,
- concomitant diseases like anemia, cancer, stroke, transient ischemic attacks, MI, hypertension, heart failure/cardiomyopathy, ischemic heart disease, diabetes, hepatic failure, or peptic ulcer disease; and
- concomitant risks for injury like risk for falls, cognitive impairment or surgery during index hospitalization.

14. Dabigatran etexilate, optionally in the form of a pharmaceutically acceptable salt thereof for use in preventing stroke in a patient suffering from atrial fibrillation according to one of the claims 8 to 13, wherein the patient has a creatinine clearance of more than 30 mL/min.