



## ARCADIA

### **AtRial Cardiopathy and Antithrombotic Drugs In prevention After cryptogenic stroke (ARCADIA) Trial Medication Information Sheet**

#### **What is in this Study Medication Information Sheet:**

This information sheet answers some common questions about the apixaban, aspirin, and placebo tablets you have been given because you are participating in the ARCADIA Trial.

#### **What the study medications are used for:**

**Aspirin** is a type of medication called an *antiplatelet drug*, and it works by helping to keep *platelets* (small blood cells needed for normal blood clotting) in the blood from sticking together and forming harmful blood clots. **Apixaban** is a type of medication called an *anticoagulant drug*, and it also helps to reduce the clotting activity in your blood in order to prevent harmful blood clots. This helps your blood flow more easily, and provides protection against a future heart attack or stroke.

#### **How to take your study medications:**

- You will take the study medications you have been given for **as long as you are participating in ARCADIA**.
- You will be given **2 bottles** of study medications.
- Each morning, you will take **1 tablet from Bottle 1 (aspirin or placebo [WHITE LABEL]) and 1 tablet from Bottle 2 (apixaban or placebo [COLORED LABEL])**.
- Each evening, you will take **1 tablet ONLY from Bottle 2 (apixaban or placebo [COLORED LABEL])**.
- Take your medications at the **same time each day**. A set schedule will help you to remember to **take the medication on time and in the right dosage**.
- Take your medications **only as directed**. Be sure there are **at least 12 hours between doses**.
- You can take your medications **with or without food**.
- Be sure to take them with a **full glass of water**.
- If you miss a dose of medication, you should take it **as soon as you remember**, unless it's **less than 6 hours** until your next dose of study medication. Then you should skip the dose you missed and **take your next dose as prescribed**.
- You will be given an **Alert Card** to carry in your wallet to let people know you are enrolled in the ARCADIA study and are taking study medications.

You will be provided with a list of medications that you should not take while you are participating in this study.

**While you are taking your study medications:**

- Tell your study doctor if you are about to start any **new medications**.
- Tell your study doctor if you **become pregnant or your partner becomes pregnant**.
- Tell all your doctors, dentists, nurses and pharmacists that you are on study medications.
  - ❖ *If you are scheduled for **surgery, dental work or other invasive procedures**, you may need to stop taking your study medications, sometimes **up to 7 days** before the procedure.*
- **Do not stop taking the study medications** without discussing it first with your study doctor.
- Keep the bottle of study tablets in a **cool, dry place at room temperature**. Heat and dampness can affect some medications so don't store the bottle in the bathroom, near a sink or anywhere the temperature might be more than 77 degrees.
- Keep the bottle away from children, preferably in a **locked cabinet**.

**Side effects you may expect from taking the study medications:**

Tell your study doctor right away if you notice any of the following;

- Weakness on one side of your body, or an inability to move a part or all of one side of your body, such as your face, arm, and leg.
- Numbness, tingling, or a feeling of heaviness on one side of your body.
- Trouble seeing, such as changes in your vision, blurring or double vision, or a sudden loss of vision in one eye.
- Trouble speaking, finding or understanding words.
- Trouble walking, such as unsteadiness, clumsiness, loss of balance and coordination, or a sudden loss of strength in your legs causing you to fall.
- Dizziness, vertigo, or sudden confusion or loss of memory.
- Abnormal, unexplained or unusual bleeding or bruising, such as bleeding that is excessive, takes a long time to stop or that occurs in an unusual place.
- Bloody or black ("tarry") bowel movements and stomach pain; dark or bloody urine.
- Red or purple blotches on your skin; yellowing of your skin or eyes.
- Severe allergic reaction: swelling of your face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing; rash; itching; tightness in the chest.
- Chest pain; severe, persistent headache; seizures.
- Fever or sore throat; loss of appetite; abnormally pale skin; unexplained weight loss; unusual tiredness or weakness.

We want to keep track of the study medication you take, so **bring all study medication bottles** to each follow-up visit.